

EXHIBIT D

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<p>UNITED STATES DISTRICT COURT DISTRICT of MINNESOTA</p> <p>-----</p> <p>In Re: Bair Hugger Forced Air Warming Products Liability Litigation</p> <p>This Document Relates To: All Actions MDL No. 15-2666 (JNE/FLM)</p> <p>-----</p> <p>DEPOSITION of THEODORE R. HOLFORD VOLUME I, PAGES 1 - 386 JULY 18, 2017</p> <p>(The following is the deposition of THEODORE R. HOLFORD, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulevard, Hartford, Connecticut, commencing at approximately 9:20 o'clock a.m., July 18, 2017.)</p>	<p>INDEX</p> <table><thead><tr><th></th><th>EXHIBITS</th><th>DESCRIPTION</th><th>PAGE MARKED</th></tr></thead><tbody><tr><td>1</td><td></td><td></td><td></td></tr><tr><td>2</td><td>EXHIBITS</td><td></td><td></td></tr><tr><td>3</td><td>Ex 1</td><td>Expert Report of Theodore R.</td><td></td></tr><tr><td>4</td><td></td><td>Holford, PhD</td><td>11</td></tr><tr><td>5</td><td>2</td><td>Holford curriculum vitae</td><td>11</td></tr><tr><td>6</td><td>3</td><td>Expert report of Jonathan M.</td><td></td></tr><tr><td>7</td><td></td><td>Samet</td><td>11</td></tr><tr><td>8</td><td>4</td><td>Albrecht October 7, 2016</td><td></td></tr><tr><td>9</td><td></td><td>deposition excerpts</td><td>23</td></tr><tr><td>10</td><td>5</td><td>Augustine Biomedical + Design</td><td></td></tr><tr><td>11</td><td></td><td>Research and Development</td><td></td></tr><tr><td>12</td><td></td><td>Report, 9/14/2007</td><td>24</td></tr><tr><td>13</td><td>6</td><td>Article, Forced-Air Warming</td><td></td></tr><tr><td>14</td><td></td><td>Design: Evaluation of Intake</td><td></td></tr><tr><td>15</td><td></td><td>Filtration, Internal Microbial</td><td></td></tr><tr><td>16</td><td></td><td>Buildup, and Airborne-</td><td></td></tr><tr><td>17</td><td></td><td>Contamination Emissions, by</td><td></td></tr><tr><td>18</td><td></td><td>Reed, et al</td><td>28</td></tr><tr><td>19</td><td>7</td><td>Article, Predicting bacterial</td><td></td></tr><tr><td>20</td><td></td><td>populations based on airborne</td><td></td></tr><tr><td>21</td><td></td><td>particulates: A study performed</td><td></td></tr><tr><td>22</td><td></td><td>in nonlaminar flow operating</td><td></td></tr><tr><td>23</td><td></td><td>rooms during joint arthroplasty</td><td></td></tr><tr><td>24</td><td></td><td>surgery, by Stocks, et al</td><td>46</td></tr><tr><td>25</td><td>8</td><td>E-mail string, 3MBH00050770-1</td><td>50</td></tr></tbody></table>		EXHIBITS	DESCRIPTION	PAGE MARKED	1				2	EXHIBITS			3	Ex 1	Expert Report of Theodore R.		4		Holford, PhD	11	5	2	Holford curriculum vitae	11	6	3	Expert report of Jonathan M.		7		Samet	11	8	4	Albrecht October 7, 2016		9		deposition excerpts	23	10	5	Augustine Biomedical + Design		11		Research and Development		12		Report, 9/14/2007	24	13	6	Article, Forced-Air Warming		14		Design: Evaluation of Intake		15		Filtration, Internal Microbial		16		Buildup, and Airborne-		17		Contamination Emissions, by		18		Reed, et al	28	19	7	Article, Predicting bacterial		20		populations based on airborne		21		particulates: A study performed		22		in nonlaminar flow operating		23		rooms during joint arthroplasty		24		surgery, by Stocks, et al	46	25	8	E-mail string, 3MBH00050770-1	50
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<p>1 APPEARANCES:</p> <p>2 On Behalf of the Plaintiffs:</p> <p>3 Michael A. Sachet and Jan M. Conlin</p> <p>4 CIRESI CONLIN L.L.P.</p> <p>5 225 South 6th Street, Suite 4600</p> <p>6 Minneapolis, Minnesota 55402</p> <p>On Behalf of Defendants:</p> <p>7 Corey L. Gordon</p> <p>8 BLACKWELL BURKE P.A.</p> <p>9 432 South Seventh Street, Suite 2500</p> <p>10 Minneapolis, Minnesota 55415</p> <p>11 ALSO APPEARING:</p> <p>12 Ronald M. Huber, Videotechnician</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 9 Article, Association of Airborne</p> <p>2 Microorganisms in the Operating</p> <p>3 Room With Implant Infections: A</p> <p>4 Randomized Controlled Trial, by</p> <p>5 Darouiche, et al 54</p> <p>6 10 Proceedings of the International</p> <p>7 Consensus Meeting on Peri-</p> <p>8 prosthetic Joint Infection 67</p> <p>9 11 Van Duren March 7, 2017</p> <p>10 transcript excerpt 77</p> <p>11 12 Article, Convection warmers --</p> <p>12 a possible source of contamination</p> <p>13 in laminar airflow operating</p> <p>14 theatres? by Tumia, et al 80</p> <p>15 13 Article, Forced-air warming</p> <p>16 and ultra-clean ventilation do</p> <p>17 not mix, by McGovern, et al 94</p> <p>18 14 Computer printout, AUGUSTINE_</p> <p>19 0005193-487 104</p> <p>20 15 Albrecht October 7, 2016</p> <p>21 deposition excerpt 123</p> <p>22 16 LogisticRegression analysis,</p> <p>23 Albrecht, March 11, 2016,</p> <p>24 Albrecht_0002275-8 135</p> <p>25 17 Gmail string 140</p>																																																																																																								

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<p>1 18 Computer printout 148</p> <p>2 19 Article, Return to theatre</p> <p>3 following total hip and knee</p> <p>4 replacement, before and after</p> <p>5 the introduction of rivaroxaban,</p> <p>6 by Jensen, et al 179</p> <p>7 20 Fisher's exact test of</p> <p>8 independence article 198</p> <p>9 21 Article, Levels of Household</p> <p>10 Mold Associated with Respiratory</p> <p>11 Symptoms in the First Year of</p> <p>12 Life in a Cohort at Risk for</p> <p>13 Asthma, by Gent, et al 201</p> <p>14 22 Chi-square test of goodness-</p> <p>15 of-fit article 208</p> <p>16 23 Graph, 3M00554267 229</p> <p>17 24 Article, Infection Control in</p> <p>18 Orthopaedic Surgery 249</p> <p>19 25 Article, Implementing effective</p> <p>20 SSI surveillance, by Gillson</p> <p>21 et al 251</p> <p>22 26 Article, Confounding in</p> <p>23 Epidemiologic Studies, by</p> <p>24 Greenland, et al 283</p> <p>25 27 Article, Statistical Methods in</p>	<p>1 PROCEEDINGS</p> <p>2 (Witness sworn.)</p> <p>3 THEODORE R. HOLFORD</p> <p>4 called as a witness, being first duly sworn,</p> <p>5 was examined and testified as follows:</p> <p>6 ADVERSE EXAMINATION</p> <p>7 BY MR. SACCHET:</p> <p>8 Q. Good afternoon, Professor Holford. My name</p> <p>9 is Michael Sacchet and I represent the plaintiffs in</p> <p>10 this litigation.</p> <p>11 Could you please state your full name for</p> <p>12 the record.</p> <p>13 A. Theodore Richard Holford.</p> <p>14 Q. And Professor Holford, have you had your</p> <p>15 deposition taken before?</p> <p>16 A. Not on this.</p> <p>17 Q. In the past?</p> <p>18 A. Yes, I have.</p> <p>19 Q. What was the subject matter of that</p> <p>20 deposition?</p> <p>21 A. Cigarette smoking.</p> <p>22 Q. How long ago?</p> <p>23 A. Ooh. It was probably eight years ago,</p> <p>24 something like that, eight, 10 years ago.</p> <p>25 Q. And were you called to offer opinion as to</p>
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<p>1 Cancer Research, by Breslow et</p> <p>2 al 297</p> <p>3 28 Article, Forced-air warming</p> <p>4 discontinued: periprosthetic</p> <p>5 joint infection rates drop,</p> <p>6 by Augustine 329</p> <p>7 29 Jonathan Borak expert report 362</p> <p>8 30 Record of Proceedings, Health-</p> <p>9 care Infection Control Practices</p> <p>10 Advisory Committee, November</p> <p>11 5-6, 2015 368</p> <p>12 31 Record of Proceedings, Health-</p> <p>13 care Infection Control Practices</p> <p>14 Advisory Committee, March 31,</p> <p>15 2016 376</p> <p>16 32 Arizant forced-air warming and</p> <p>17 SSI prevention: Talking points</p> <p>18 for sales, 3MBH00001336-7 381</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 biostatistics?</p> <p>2 A. Yes.</p> <p>3 Q. Epidemiology?</p> <p>4 A. It was in regard to a statistical review</p> <p>5 that I did of an epidemiology calculation paper -- or</p> <p>6 chapter of a book, actually.</p> <p>7 Q. What was the chapter of that book?</p> <p>8 A. It was a chapter dealing with lung cancer</p> <p>9 trends, and they were relating it to smoking.</p> <p>10 Q. Okay. And were the studies that you relied</p> <p>11 on in that chapter of the book observational studies?</p> <p>12 A. Yes.</p> <p>13 Q. What --</p> <p>14 How many studies were there?</p> <p>15 A. I don't recall. It was a -- quite a long --</p> <p>16 quite a long time ago. I think some of it was</p> <p>17 population data as I recall, but it's been -- been</p> <p>18 quite a long time; I've forgotten the details of it.</p> <p>19 Q. And who retained you to provide expert</p> <p>20 testimony in that litigation?</p> <p>21 A. It was the tobacco companies. They --</p> <p>22 they -- I was -- I -- they de -- deposed me. They</p> <p>23 subpoenaed me and wanted me to be a witness.</p> <p>24 MR. GORDON: I -- I think he's not</p> <p>25 understanding -- he's not tracking what you mean by</p>

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<p style="text-align: right;">Page 9</p> <p>1 "retained." 2 MR. SACCHET: Yeah. I'll -- I'll clarify 3 the question. 4 MR. GORDON: Thank you. 5 Q. So the tobacco industry was examining 6 adversely or -- 7 A. Yes. 8 Q. Okay. And who were you -- 9 A. Well I -- yeah, I guess it was -- 10 Yeah. They called me and it was because I 11 had been critical of one of the papers -- one of the 12 chapters at the time, and that's why I was deposed. 13 Q. What were you critical about? 14 A. Details on their analysis. 15 Q. And their analysis is that there was not 16 causation with respect to tobacco use and lung cancer? 17 A. No. No. It was -- 18 The analysis had to do with looking at 19 trends, lung cancer trends -- 20 Q. Okay. 21 A. -- and -- and disease trends, and that's an 22 area that's been of particular statistical interest. 23 Q. These were time trends? 24 A. Yes. 25 Q. Any other times in which you've offered</p>	<p style="text-align: right;">Page 11</p> <p>1 of the exhibit, please determine whether it is a full 2 and accurate copy of the report you have submitted in 3 this case. 4 (Exhibit 1 was marked for 5 identification.) 6 MR. GORDON: This is just his report without 7 the CV? 8 MR. SACCHET: Yeah. I'll get there. 9 MR. SACCHET: And attached to your -- 10 Well I'll let you look at it first. 11 (Exhibit 2 was marked for 12 identification.) 13 A. Yes, it appears to be complete. 14 Q. And you also attached your curriculum vitae 15 to your report; correct? 16 A. Yes. 17 Q. And is that an accurate copy of your CV from 18 what you can tell? 19 A. It appears to be so, yes. 20 MR. SACCHET: And as another housekeeping 21 matter, we are going to mark Dr. Samet's report as 22 Exhibit 3. 23 (Exhibit 3 was marked for 24 identification.) 25 BY MR. SACCHET:</p>
<p style="text-align: right;">Page 10</p> <p>1 expert testimony, whether it be in a deposition or 2 through an expert report? 3 A. No. 4 Q. You're familiar with the rules of 5 deposition? 6 A. I think so. 7 Q. I'll just quickly review them so we're on 8 the same page. 9 As you know, I'll be asking you questions 10 and you'll be answering un -- them under oath. If you 11 don't understand a question, let me know and I'll do 12 my best to clarify. For purposes of the court 13 reporter, it's best if you allow me to finish my 14 question before you attempt to answer it so that we 15 have a clear record. And last and perhaps most 16 importantly, if you could answer all questions 17 verbally as opposed to nodding or shaking your head so 18 we have an opportunity to record your answer. Is that 19 agreeable? 20 A. Yes. 21 Q. In this litigation you've drafted a report; 22 correct, professor? 23 A. That's correct. 24 Q. We'll be marking this report as Exhibit 1. 25 I see you have one in front of you, but for the sake</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. The report that you have filed in this case 2 responds to Dr. Samet's report; is that correct, Dr. 3 Holford? 4 A. Yes, that's correct. 5 Q. And that appears to be a full version of Dr. 6 Samet's report? 7 A. It appears to be, yes. 8 Q. Based on your curriculum vitae, I understand 9 that you have a B.A. in mathematics and chemistry; is 10 that correct? 11 A. That's correct. 12 Q. And you earned those degrees from Andrews 13 University? 14 A. Yes. 15 Q. Where is Andrews? 16 A. Berrian Springs, Michigan. 17 Q. Is that where you're from? 18 A. No. 19 Q. Why did you decide to go there? 20 A. Well my parents basically just made it clear 21 that that's where they wanted me to go. 22 Q. Okay. And you subsequently earned a Ph.D. 23 from Yale University in biometrics; correct? 24 A. That's correct. 25 Q. And biometrics is the application of</p>

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<p style="text-align: right;">Page 13</p> <p>1 statistical methods to biological data?</p> <p>2 A. Basically, yes.</p> <p>3 Q. So in large part the focus is on statistics;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. What is the relationship of biostatistics to</p> <p>7 epidemiology?</p> <p>8 A. Epidemiologists use biostatistics a lot in</p> <p>9 their -- in their research, so there's often a</p> <p>10 collaborative arrangement between epidemiologists</p> <p>11 and -- and -- and statisticians.</p> <p>12 Q. They are two separate fields though;</p> <p>13 correct?</p> <p>14 A. They are, yes.</p> <p>15 Q. You do not have a degree in epidemiology;</p> <p>16 correct?</p> <p>17 A. No.</p> <p>18 Q. You do not have clinical training in</p> <p>19 epidemiology?</p> <p>20 A. Most epidemiologists are not clinicians --</p> <p>21 or many epidemiologists are not, so no, that's</p> <p>22 correct.</p> <p>23 Q. Some are; correct?</p> <p>24 A. Some are.</p> <p>25 Q. Dr. Samet is; correct?</p>	<p style="text-align: right;">Page 15</p> <p>1 A. I've done a fair amount on cancer. It's not</p> <p>2 the only thing I've worked on, but yes.</p> <p>3 Q. Other topics that I noticed when I reviewed</p> <p>4 some of your literature were articles on contraception</p> <p>5 and pregnancy.</p> <p>6 A. That was early on. It was -- it was more on</p> <p>7 looking at the potential side effects of contraceptive</p> <p>8 use.</p> <p>9 Q. What would you say are the primary topics of</p> <p>10 your research in addition to cancer, smoking,</p> <p>11 contraception and pregnancy?</p> <p>12 A. Air pollution is another thing that I've</p> <p>13 worked on. Yeah, air pollution and childhood asthma.</p> <p>14 Q. Okay. So I've read a couple of the articles</p> <p>15 and what I can tell is that you have researched the</p> <p>16 impact of particulates on respiratory disease;</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. Have you ever researched the impact of</p> <p>20 particulates on other types of disease?</p> <p>21 A. Not that I recall.</p> <p>22 Q. So it's limited to the impact on respiratory</p> <p>23 diseases.</p> <p>24 A. Yes, particularly childhood -- childhood</p> <p>25 asthma.</p>
<p style="text-align: right;">Page 14</p> <p>1 A. Yes.</p> <p>2 Q. You are not a medical doctor.</p> <p>3 A. No, I am not.</p> <p>4 Q. And you are not an anesthesiologist.</p> <p>5 A. No.</p> <p>6 Q. And you do not have experience in</p> <p>7 arthroplasty; correct?</p> <p>8 A. No.</p> <p>9 Q. The majority of your professional career has</p> <p>10 been at Yale University in a research and teaching</p> <p>11 capacity; correct?</p> <p>12 A. Yes, that's correct.</p> <p>13 Q. I saw some examples on your curriculum vitae</p> <p>14 in which you've gone elsewhere, I think Oxford</p> <p>15 University and maybe a few other locations, to do</p> <p>16 other work. Could you describe those -- those</p> <p>17 opportunities briefly?</p> <p>18 A. Yes. At Oxford I was on -- I had a</p> <p>19 sabbatical year which I took at Oxford University.</p> <p>20 Q. And what did you do during the sabbatical</p> <p>21 year?</p> <p>22 A. I -- I did research, I taught a class, and</p> <p>23 I -- I basically worked on my research.</p> <p>24 Q. Okay. With respect to the research that you</p> <p>25 have published, you have focused on cancer; correct?</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Any other topics of focus?</p> <p>2 A. Oh, I've occasionally done things related to</p> <p>3 in -- infectious diseases. My dissertation research</p> <p>4 was on schistosomiasis and statistical modeling for</p> <p>5 that. I've done work with a clinical trial on spinal</p> <p>6 cord injuries, the treatment for spinal cord injury.</p> <p>7 Q. Okay.</p> <p>8 A. Lots of work in cancer of course,</p> <p>9 various -- various aspects of it. Currently, I'm</p> <p>10 doing a lot of work on population models for cancer,</p> <p>11 mostly lung cancer, but --</p> <p>12 Q. Okay.</p> <p>13 A. -- yeah, it's related.</p> <p>14 Q. You have not researched computational fluid</p> <p>15 dynamics; correct?</p> <p>16 A. No.</p> <p>17 Q. You have not performed research on operating</p> <p>18 room airflow; correct?</p> <p>19 A. On operating --</p> <p>20 On what?</p> <p>21 Q. Room airflow.</p> <p>22 A. No.</p> <p>23 Q. How about filtration of operating rooms?</p> <p>24 A. No.</p> <p>25 Q. What about filtration of medical devices?</p>

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<p>1 A. No.</p> <p>2 Q. What about anesthesia?</p> <p>3 A. No.</p> <p>4 Q. Microbiology?</p> <p>5 A. No.</p> <p>6 Q. Orthopedics?</p> <p>7 A. No.</p> <p>8 Q. So I assume that means no for deep joint</p> <p>9 infection.</p> <p>10 A. Yes.</p> <p>11 Q. Are you offering testimony as to any of</p> <p>12 those subject matters?</p> <p>13 A. I'm offering testimony on statistical</p> <p>14 aspects that relate to the -- the Bair Hugger. I</p> <p>15 don't know if you think that's related or not.</p> <p>16 Q. But as to the core topic of those subject</p> <p>17 matters --</p> <p>18 A. Those subjects, no.</p> <p>19 Q. -- you are not opining --</p> <p>20 A. No, I am not.</p> <p>21 Q. -- about them discretely; correct?</p> <p>22 A. That's correct.</p> <p>23 Q. So you are not responding to the reports of</p> <p>24 Dr. Said Elghobashi, for example, --</p> <p>25 A. No.</p>	<p>1 subject matter; correct?</p> <p>2 A. Yes.</p> <p>3 Q. To the extent that Dr. Samet's report</p> <p>4 includes his experience as a medical doctor, you do</p> <p>5 not have expertise to respond to those opinions;</p> <p>6 correct?</p> <p>7 A. Not the particular ones that related to the</p> <p>8 medical opinions, yes.</p> <p>9 Q. To the extent that Dr. Samet's report relies</p> <p>10 on his training in anesthesiology, you do not have</p> <p>11 expertise to respond those conclusions; correct?</p> <p>12 A. That's correct.</p> <p>13 Q. To the extent that Dr. Samet's opinions</p> <p>14 hinge on his experience as a clinical epidemiologist,</p> <p>15 you do not have experience to respond to those</p> <p>16 opinions; correct?</p> <p>17 A. I have not been a clinical epidemiologist,</p> <p>18 no. I have worked -- worked with a lot of others that</p> <p>19 have done, you know, clinical epidemiology work so</p> <p>20 I've been involved with people doing that kind of</p> <p>21 work, but primarily from a statistical perspective.</p> <p>22 Q. So you don't have expertise to respond to</p> <p>23 the clinical side of epidemiology; correct?</p> <p>24 A. Correct.</p> <p>25 Q. So you are not responding to Dr. Samet's</p>
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<p>1 Q. -- which is a report on computational fluid</p> <p>2 dynamics.</p> <p>3 A. Yeah. No, I am not.</p> <p>4 Q. And you are not responding to Dr. Jarvis's</p> <p>5 report from a microbiology standpoint; correct?</p> <p>6 A. Not from a microbiology standpoint.</p> <p>7 Q. Is your testimony limited to the McGovern</p> <p>8 study?</p> <p>9 A. Primarily, yes.</p> <p>10 Q. What do you mean by "primarily?"</p> <p>11 A. Well that -- that was the focus of what I</p> <p>12 was looking at, was the McGovern study.</p> <p>13 Q. Your report says that "This report is a</p> <p>14 review of the observational study of risk for deep</p> <p>15 joint infection following the use of Bair Hugger</p> <p>16 warming device during hip and knee replacement</p> <p>17 surgery...;" correct?</p> <p>18 A. Yes.</p> <p>19 MR. GORDON: To clarify, subsequent to his</p> <p>20 report and -- and in light of Dr. Samet's reliance on</p> <p>21 the newly published Augustine paper, we've asked him</p> <p>22 to take a look at that.</p> <p>23 Q. To the extent that Dr. Samet's causal</p> <p>24 inference depends on factors outside of the McGovern</p> <p>25 study, you do not have an expertise to opine on that</p>	<p>1 opinions to the extent that they rely on a clinical</p> <p>2 perspective of epidemiology; correct?</p> <p>3 A. Not the clinical perspective, that's right.</p> <p>4 Q. To the extent Dr. Samet's opinions rely on</p> <p>5 his experience with filtration, you are not responding</p> <p>6 to those opinions; are you?</p> <p>7 A. No.</p> <p>8 Q. And to the extent that Dr. Samet relies on</p> <p>9 his experience in particulate matter, you're not</p> <p>10 responding to those opinions; are you?</p> <p>11 A. No.</p> <p>12 Q. You nonetheless opine, however, that</p> <p>13 particles are simply an intermediate proxy for deep</p> <p>14 joint infection; correct?</p> <p>15 A. I'm sorry, could you repeat that?</p> <p>16 Q. Your report states that particles are at</p> <p>17 most an intermediate outcome that has not been shown</p> <p>18 to directly relate to the outcome of interest, deep</p> <p>19 joint infection; correct?</p> <p>20 A. Yes.</p> <p>21 Q. If you do not have the expertise that Dr.</p> <p>22 Samet has in airborne particulate matter, on what</p> <p>23 basis are you making that conclusion?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>

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<p>1 A. I'm sorry, could you repeat the question?</p> <p>2 Q. To the extent that you have concluded that</p> <p>3 particles are at most an intermediate outcome that has</p> <p>4 not been shown to relate to the outcome of interest,</p> <p>5 deep joint infection, on what basis are you making</p> <p>6 that conclusion?</p> <p>7 A. I'm basing that on the -- on the -- some of</p> <p>8 the manuscripts related -- related to that and some of</p> <p>9 the other testimony and things that I've related to</p> <p>10 that or related to the pub -- in terms of the Bair</p> <p>11 Hugger.</p> <p>12 Q. Which manuscripts?</p> <p>13 A. I'm -- let's see. I've --</p> <p>14 There's some of the work that the</p> <p>15 Albright -- Albrecht, is that -- the person that works</p> <p>16 with Augustine, and some of -- some of that work where</p> <p>17 they were -- where they were trying to look at the --</p> <p>18 the output from the device and look at the infection,</p> <p>19 look -- looking for organisms deposited on agar plates</p> <p>20 from -- from that, it was one of those papers.</p> <p>21 I've -- I've forgotten exactly which -- which the</p> <p>22 author was, but I re -- remember that recollection, so</p> <p>23 that's the basis of that.</p> <p>24 Q. And that's your only basis?</p> <p>25 A. That's primarily my only basis, yes.</p>	<p>1 what I relied on in writing this, yes.</p> <p>2 Q. Have you reviewed anything since you filed</p> <p>3 your report until today in addition to those sources?</p> <p>4 A. I reviewed the recent paper by Augustine</p> <p>5 and, let's see, what else? That's most of what I --</p> <p>6 what I have -- have re -- reviewed. I -- I saw some</p> <p>7 of -- a small piece of Augustine's dep -- deposition,</p> <p>8 and that's -- that's about it.</p> <p>9 Q. Okay. I'm going to circle back to</p> <p>10 Albrecht's deposition testimony with respect to the</p> <p>11 testing that he did on particles and bacteria.</p> <p>12 (Exhibit 4 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. SACCHET:</p> <p>15 Q. This is an excerpt of Mr. Albrecht's</p> <p>16 deposition; correct?</p> <p>17 A. Yes.</p> <p>18 Q. And if you could turn to page seven in the</p> <p>19 bottom right-hand corner, or internal page 23 in the</p> <p>20 top right-hand corner --</p> <p>21 MR. GORDON: Did you mark this?</p> <p>22 THE REPORTER: Yes.</p> <p>23 MR. SACCHET: I did.</p> <p>24 THE REPORTER: That's four.</p> <p>25 Q. -- and you'll see line 23 of page 23 says,</p>
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<p>1 Q. You know that Mr. Albrecht is not a</p> <p>2 microbiologist; right?</p> <p>3 A. Yes.</p> <p>4 Q. You have not reviewed any published studies</p> <p>5 regarding the link between particles and bacteria and</p> <p>6 deep joint infection?</p> <p>7 A. No, that's not been -- been my primary</p> <p>8 focus.</p> <p>9 Q. So with respect to the conclusion that</p> <p>10 particles are at most an intermediate outcome that has</p> <p>11 not been shown to directly relate to the outcome of</p> <p>12 interest, deep joint infection, you are solely relying</p> <p>13 on Albrecht's manuscript.</p> <p>14 A. His manuscript and his testimony where he</p> <p>15 was describing how he was trying to deposit organisms</p> <p>16 onto agar plates and -- and that kind of stuff. He</p> <p>17 was --</p> <p>18 That was not successful, as I recall.</p> <p>19 Q. And you're referring to his deposition</p> <p>20 transcript; correct?</p> <p>21 A. Yes.</p> <p>22 Q. Have you listed everything that you have</p> <p>23 relied on on page 14 of your report, which outlines 19</p> <p>24 different sources?</p> <p>25 A. I think so. That's the -- that's basically</p>	<p>1 "...Exhibit 1 is a report for -- from certain work --</p> <p>2 research activities that were done at the Regina</p> <p>3 Surgery Center..." Do you see that, --</p> <p>4 A. Yes.</p> <p>5 Q. -- Professor Holford?</p> <p>6 A. Uh-huh.</p> <p>7 Q. Is this one of the exhibits that you rely on</p> <p>8 with respect to Mr. Albrecht's testimony regarding</p> <p>9 bacteria?</p> <p>10 MR. GORDON: Do you have that exhibit?</p> <p>11 MR. SACCHET: I do.</p> <p>12 A. I -- I think this is -- this is -- this is</p> <p>13 the one, yes.</p> <p>14 Q. Did you rely on the deposition testimony or</p> <p>15 the exhibits to the deposition when you concluded that</p> <p>16 particles are at most an indeterminate outcome?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question.</p> <p>19 A. I was -- I was relying primarily on the --</p> <p>20 on the deposition.</p> <p>21 Q. Have you seen the Exhibit 1 that was marked</p> <p>22 at this deposition?</p> <p>23 A. I -- I don't recall.</p> <p>24 (Exhibit 5 was marked for</p> <p>25 identification.)</p>

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<p style="text-align: right;">Page 25</p> <p>1 BY MR. SACCHET:</p> <p>2 Q. Does this document refresh your recollection</p> <p>3 as to whether you have reviewed Exhibit 1 of the</p> <p>4 Albrecht deposition?</p> <p>5 A. No. I did not see this document.</p> <p>6 Q. You've never seen the document before.</p> <p>7 A. No.</p> <p>8 Q. So you only relied on the deposition</p> <p>9 transcript in determining that particles are at most</p> <p>10 an indeterminate outcome of deep joint infection.</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question, assumes facts not in evidence.</p> <p>13 A. I think what I'm saying is that this -- this</p> <p>14 document is not -- was -- was not what I had</p> <p>15 considered.</p> <p>16 Q. Did you review any of the exhibits that were</p> <p>17 marked at the Albrecht deposition with respect to the</p> <p>18 testimony regarding testimony of particulates versus</p> <p>19 bacteria?</p> <p>20 A. I didn't review the exhibits, no.</p> <p>21 Q. Okay. Let's go back to the transcripts</p> <p>22 then. And I believe your conclusion about particles</p> <p>23 being related to bacteria can be found on page 19 in</p> <p>24 the bottom right-hand corner, or page 73, which is the</p> <p>25 internal page.</p>	<p style="text-align: right;">Page 27</p> <p>1 different than the 505?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, lack of foundation.</p> <p>4 A. I have no idea what they were using. I</p> <p>5 mean --</p> <p>6 Yeah, I don't -- I don't know.</p> <p>7 Q. This exhibit makes clear that testing was</p> <p>8 done on the 505; correct?</p> <p>9 A. Yes.</p> <p>10 Q. Are you aware that the model 505 uses a</p> <p>11 different filter than the Bair Hugger model 750 and</p> <p>12 775?</p> <p>13 A. No. I -- I'm not familiar with -- with</p> <p>14 which filters are used on them.</p> <p>15 Q. You cited the Reed article in your reference</p> <p>16 list; correct?</p> <p>17 A. Yes.</p> <p>18 Q. Did you review that article?</p> <p>19 A. I did look at that article, yes.</p> <p>20 Q. So you reviewed the article but you're not</p> <p>21 aware that there are two different filter efficiencies</p> <p>22 for the model 505 versus the model 750.</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question.</p> <p>25 A. I was not reviewing the particular filters.</p>
<p style="text-align: right;">Page 26</p> <p>1 MR. GORDON: What page?</p> <p>2 MR. SACCHET: Nineteen TSG, internal 73.</p> <p>3 MR. GORDON: Oh, I see. All right.</p> <p>4 Q. And line 16 states, "Okay. Did -- so you --</p> <p>5 you found that there were particles of various sizes,</p> <p>6 various counts coming out of the Bair Hugger?"</p> <p>7 Response: "Yes, we did.</p> <p>8 "Question: But you really didn't find much</p> <p>9 in the way of bacteria coming out?"</p> <p>10 Response: "We did not."</p> <p>11 A. Yes.</p> <p>12 Q. Did you review the other sections of this</p> <p>13 deposition transcript aside from that conclusion?</p> <p>14 A. That's most of what I -- what I noticed in</p> <p>15 that report, yes.</p> <p>16 Q. Okay. If I could draw your attention to the</p> <p>17 Exhibit 5, which is the report that is cited in this</p> <p>18 deposition transcript, the last page, page 12, notes</p> <p>19 that, in the first bullet point, "...testing done in</p> <p>20 our lab rated the 505 intake filter at roughly 94</p> <p>21 percent;" correct?</p> <p>22 A. Yes, that's what it says.</p> <p>23 Q. Do you have any reason to doubt that the</p> <p>24 testing that was done with respect to Mr. Albrecht's</p> <p>25 testimony in this transcript involved a device</p>	<p style="text-align: right;">Page 28</p> <p>1 (Exhibit 6 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. SACCHET:</p> <p>4 Q. If you could turn your attention to the</p> <p>5 column in the right-hand side on page one, the first</p> <p>6 full sentence starts with "Prior research..." Do you</p> <p>7 see that, Dr. Holford? On the first page, right-hand</p> <p>8 column.</p> <p>9 Text, not abstract.</p> <p>10 A. "Prior research," is that what you said?</p> <p>11 Q. Yes.</p> <p>12 A. Yeah. Okay.</p> <p>13 Q. "Prior research has rated the intake</p> <p>14 filtration efficiency of legacy FAW devices (Bair</p> <p>15 Hugger 505, Arizant Healthcare) at 93.8 percent for an</p> <p>16 'older' filter model in clinical use (200708C) and</p> <p>17 61.3 percent for a 'newer' filter model (200708D)</p> <p>18 scheduled to replace the older filter in clinical</p> <p>19 use." Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Does that make clear that there are two</p> <p>22 different filtration capacities?</p> <p>23 A. Yes, it does.</p> <p>24 Q. And the older filter that we're talking</p> <p>25 about has been denominated as the Bair Hugger 505;</p>

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<p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And below that, do you see the reference to</p> <p>4 Bair Hugger 750 in the next paragraph?</p> <p>5 A. Yes.</p> <p>6 Q. Are you now aware that there are two</p> <p>7 different filtration efficiencies?</p> <p>8 A. Yes.</p> <p>9 Q. If we could now turn back to the deposition</p> <p>10 transcript, which has been marked as Exhibit 4, and if</p> <p>11 you could turn to page 40, internal page 40, and line</p> <p>12 nine states, "We were assessing filtration efficiency</p> <p>13 and that dealt with particles on the in and out</p> <p>14 stream, because it's very important in case there are</p> <p>15 resident airborne microbes that could be sucked in and</p> <p>16 delivered through." Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Based on that testimony and the documents we</p> <p>19 have reviewed, is it clear to you that Mr. Albrecht</p> <p>20 was conducting testing on the filter of the model 505?</p> <p>21 MR. GORDON: Object to the form of the</p> <p>22 question, lacks foundation.</p> <p>23 A. I'm not -- I guess I'm not really under --</p> <p>24 understanding if he's testing the filter or if he's</p> <p>25 testing -- you know, filter per se, because as I -- as</p>	<p>1 MR. GORDON: Same object -- same objection.</p> <p>2 A. It would be doing that, but I've already</p> <p>3 said that this -- this particular document was not</p> <p>4 something that I -- I was reviewing.</p> <p>5 Q. Well this is a document that's referenced in</p> <p>6 the deposition of the testing that was done with</p> <p>7 respect to what you're relying on; correct?</p> <p>8 MR. GORDON: Object to the form of the</p> <p>9 question, and also misconstrues the evidence.</p> <p>10 A. What I -- what I think I've -- what I said</p> <p>11 was -- is I looked at the deposition, I was -- I did</p> <p>12 not refer to the -- directly to the -- to all -- to</p> <p>13 all of the exhibits in it.</p> <p>14 Q. So now that we're reviewing the exhibit,</p> <p>15 that is a document -- the testing that was performed</p> <p>16 by Mr. Albrecht, does that enlighten your viewpoint?</p> <p>17 MR. GORDON: Well object to the form of the</p> <p>18 question. Counsel, you've shown him one exhibit.</p> <p>19 There were multiple exhibits marked in the</p> <p>20 August -- at the Albrecht deposition.</p> <p>21 Q. We can go back to the line in the exhibit</p> <p>22 which we reviewed just a moment ago on page --</p> <p>23 internal page 23 that says, "...Exhibit 1 is a report</p> <p>24 for -- from certain work -- research activities that</p> <p>25 were done at the Regina Surgery Center..." Do you</p>
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<p>1 I understand it, there's a whole mechanism that's --</p> <p>2 that's involved here. It's not just the filter.</p> <p>3 Q. Okay. Let's look at what's been marked as</p> <p>4 Exhibit 5, the report.</p> <p>5 A. Okay.</p> <p>6 Q. Do you see point four?</p> <p>7 A. Yeah.</p> <p>8 Q. Says, "Impaction: Impaction sampling will</p> <p>9 be performed on the air stream in the distal region of</p> <p>10 the hose on a non-specific growth media."</p> <p>11 A. Okay.</p> <p>12 Q. Are you aware that in order to test whether</p> <p>13 anything would come out of the hose, it would first</p> <p>14 need to travel through the filter of the device?</p> <p>15 A. Yes.</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, lack of foundation.</p> <p>18 Q. You are aware of that.</p> <p>19 A. It would have --</p> <p>20 It would apparently go through -- through</p> <p>21 the filter, yes.</p> <p>22 Q. So with respect to this testing, the model</p> <p>23 505 was tested to determine whether particles moved</p> <p>24 through the filter and out of the distal hose;</p> <p>25 correct?</p>	<p>1 have any reason to doubt --</p> <p>2 MR. GORDON: But that -- that's true,</p> <p>3 counsel, but you're -- you've jumped ahead about 50</p> <p>4 pages in the deposition, and I -- I was there, I took</p> <p>5 it. There were other exhibits marked. We were not</p> <p>6 talking exclusively about Exhibit 1, and I think</p> <p>7 that's really unfair.</p> <p>8 MR. SACCHET: There's one other exhibit I</p> <p>9 can maintain that regards the testimony that Mr.</p> <p>10 Albrecht gave in that deposition, and that has been</p> <p>11 marked as Albrecht Exhibit 3. Is that what you're</p> <p>12 referring to, Mr. Gordon?</p> <p>13 MR. GORDON: I don't know. You'd have to</p> <p>14 show it to me. But there was -- it wasn't just the</p> <p>15 Regina testing; there were three different tests.</p> <p>16 Q. Okay. So let's just look at the deposition</p> <p>17 testimony if you're unwilling to conclude that</p> <p>18 Exhibit 1 is -- is the foundation for the testimony</p> <p>19 that Mr. Albrecht provided.</p> <p>20 On line 36 of the deposition transcript --</p> <p>21 or excuse me, page 36, if you could turn to that, Dr.</p> <p>22 Holford, line five states:</p> <p>23 "So you were looking for particles coming</p> <p>24 out, that were being blown out of the Bair Hugger --</p> <p>25 "Uh-huh."</p>

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<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And the subsequent lines say:</p> <p>4 "Question: -- that was the particle</p> <p>5 counting?</p> <p>6 "But with the impaction counting you were</p> <p>7 looking to see if there were any actual bacteria that</p> <p>8 were being blown out of the Bair Hugger?</p> <p>9 "Correct."</p> <p>10 A. Yes.</p> <p>11 Q. Does that provide an example of the</p> <p>12 testimony that you relied on in determining that Mr.</p> <p>13 Albrecht's testing involved whether Bair Hugger --</p> <p>14 whether bacteria came out of the Bair Hugger?</p> <p>15 A. Are you asking for --</p> <p>16 I don't understand the -- the question. Are</p> <p>17 you asking was he looking at any -- whether or not any</p> <p>18 particles were coming out of the Bair Hugger --</p> <p>19 Q. Does this --</p> <p>20 A. -- or are you asking whether there were</p> <p>21 bacteria that were coming out of the Bair Hugger?</p> <p>22 Q. Was Mr. Albrecht trying to determine that</p> <p>23 bacteria were being blown out of the Bair Hugger?</p> <p>24 A. He was trying to do that, yes.</p> <p>25 Q. Okay. Do you know how he was trying to</p>	<p>1 MR. SACCHET: During the testing that Mr.</p> <p>2 Albrecht discusses in his deposition transcript that</p> <p>3 you relied on in opining that particles are at best an</p> <p>4 indeterminate outcome of bacteria.</p> <p>5 A. I'm opining that -- you're looking --</p> <p>6 If you're just looking at particles, that's</p> <p>7 not looking at whether bacteria are on those</p> <p>8 particles.</p> <p>9 Q. And you have stated that --</p> <p>10 A. My understanding was what he was looking at</p> <p>11 is whether or not there were particles.</p> <p>12 Q. Okay. And you have stated that the</p> <p>13 foundation for your testimony that particles are at</p> <p>14 most an indeterminate outcome for bacteria is the</p> <p>15 Albrecht testing; correct?</p> <p>16 A. If -- if you're not looking -- if you're not</p> <p>17 specifically looking at what those particles are, then</p> <p>18 that's indirect evidence --</p> <p>19 Q. Are you --</p> <p>20 A. -- is what I'm -- what I'm saying.</p> <p>21 Q. Okay. Are you --</p> <p>22 A. Is that --</p> <p>23 Q. Are you aware that Mr. Albrecht was only</p> <p>24 testing whether bacteria could be cultured from the</p> <p>25 air that came through the hose?</p>
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<p>1 sample whether bacteria were coming out of the Bair</p> <p>2 Hugger?</p> <p>3 A. As I've said, this is not really my area,</p> <p>4 but I -- my understanding was the -- that the kinds of</p> <p>5 things that he was doing is blowing it on agar plates</p> <p>6 and things like that.</p> <p>7 Q. Do you know what he was blowing it out of?</p> <p>8 A. The Bair Hugger, this -- this device.</p> <p>9 Q. Do you know whether he was blowing it out of</p> <p>10 the hose or out of the blanket?</p> <p>11 A. I -- I --</p> <p>12 It's been a while since I read that. I</p> <p>13 think it was out of the -- out of the blanket, but I</p> <p>14 may be -- I may be --</p> <p>15 I don't recall -- really recall.</p> <p>16 Q. Do you know whether bacteria was tested at</p> <p>17 the surgical site?</p> <p>18 A. At --</p> <p>19 During the surgery?</p> <p>20 Q. Was bacteria being collected at the surgical</p> <p>21 site?</p> <p>22 MR. GORDON: At what point?</p> <p>23 THE WITNESS: At what point?</p> <p>24 MR. SACCHET: During the testing.</p> <p>25 MR. GORDON: Which -- which testing?</p>	<p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 A. I think he was trying to, yeah, culture</p> <p>4 that -- what was coming out of the hose, yes.</p> <p>5 Q. Mr. Albrecht did not conduct testing to</p> <p>6 determine whether disruption in airflow currents in</p> <p>7 the operating room caused bacteria to enter the</p> <p>8 surgical site; correct?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question, assumes facts not in evidence, lack of</p> <p>11 foundation.</p> <p>12 A. Yeah. I'm not under -- really understanding</p> <p>13 what your question is. I --</p> <p>14 Q. You reviewed Mr. Albrecht's transcript; --</p> <p>15 A. Yes.</p> <p>16 Q. -- correct?</p> <p>17 Did you see any mention in the transcript as</p> <p>18 to whether Mr. Albrecht did any testing beyond simply</p> <p>19 sampling bacteria out of the hose?</p> <p>20 A. Do you mean taking a swab out of -- of -- in</p> <p>21 the hose itself, --</p> <p>22 Q. No.</p> <p>23 A. -- is that what you're saying?</p> <p>24 Q. I'm saying the only testing that Mr.</p> <p>25 Albrecht did was collecting bacteria in an agar plate</p>

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<p>1 from air that came out of the hose of the device.</p> <p>2 A. He was trying to do that, yes.</p> <p>3 Q. And that's the only testing that he did.</p> <p>4 A. No. He was doing other -- other testing. I</p> <p>5 mean there was more to that ex -- those experiences he</p> <p>6 was doing. He was trying a number of different</p> <p>7 things.</p> <p>8 Q. In terms of bacterial collection, did he do</p> <p>9 anything else?</p> <p>10 A. He also swabbed, I think, the -- the -- the</p> <p>11 tube.</p> <p>12 Q. Did he do anything else with respect to</p> <p>13 either swabbing the interior of the tube or collecting</p> <p>14 bacteria in an agar plate from the air that came</p> <p>15 directly out of the hose?</p> <p>16 A. I don't recall. I don't recall whether he</p> <p>17 did or not.</p> <p>18 Q. So you don't recall whether Mr. Albrecht did</p> <p>19 any testing to see whether the Bair Hugger created</p> <p>20 convection currents that caused bacteria in the</p> <p>21 operating room to go to the surgical site.</p> <p>22 A. I don't recall seeing any direct evidence</p> <p>23 of -- of that.</p> <p>24 Q. And you're aware that Dr. Samet has opined</p> <p>25 that there are two mechanisms of infection; correct?</p>	<p>1 A. Yes.</p> <p>2 Q. So there is an entirely separate mechanism</p> <p>3 which involves air being generated in the operating</p> <p>4 room --</p> <p>5 A. Yes.</p> <p>6 Q. -- that causes bacteria to land on the</p> <p>7 surgical site.</p> <p>8 A. Right.</p> <p>9 Q. Mr. Albrecht's test -- Mr. Albrecht's</p> <p>10 testing was about air coming out of the hose into an</p> <p>11 agar plate; correct?</p> <p>12 A. Yes.</p> <p>13 MR. GORDON: Objection, lack of foundation.</p> <p>14 Q. That does not directly involve whether</p> <p>15 airflow created currents that caused bacteria to enter</p> <p>16 the surgical site.</p> <p>17 A. It might, but it -- but -- but --</p> <p>18 Yeah. I mean it's not -- it's not directly</p> <p>19 testing it while the operation is -- is being</p> <p>20 conducted. He's -- he's trying to get indirect</p> <p>21 evidence of that -- that -- that -- that mechanism of</p> <p>22 where the infection could have been caused.</p> <p>23 Q. So to the extent that you have concluded</p> <p>24 based on Mr. Albrecht's testimony that particles are</p> <p>25 at most an indeterminate outcome -- intermediate</p>
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<p>1 A. Yes.</p> <p>2 Q. One mechanism is bacteria coming directly</p> <p>3 from the Bair Hugger device itself; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And the other mechanism is from the air --</p> <p>6 from the airflow being generated from the Bair</p> <p>7 Hugger --</p> <p>8 A. Yes.</p> <p>9 Q. -- causing bacteria to enter the surgical</p> <p>10 site; correct?</p> <p>11 A. Yes.</p> <p>12 Q. So you're not aware of whether Mr. Albrecht</p> <p>13 did any testing that goes to the second causal</p> <p>14 mechanism; correct?</p> <p>15 A. Well I mean I think the -- the mechanism</p> <p>16 we -- we've talked about where he's looking at the --</p> <p>17 at what came out -- came out of the -- out of the</p> <p>18 device, my assumption is that he was interested in</p> <p>19 that because that -- that would then en -- enter</p> <p>20 the -- the -- the air around the -- where -- where the</p> <p>21 surgery was being conducted, and that that would be a</p> <p>22 mode of -- for the -- for the second mode of -- of</p> <p>23 infection that Samet is talking about.</p> <p>24 Q. Dr. Samet does not conflate the first</p> <p>25 mechanism with the second mechanism; correct?</p>	<p>1 outcome of deep joint infections, it relates solely to</p> <p>2 the first causal mechanism that Dr. Samet described in</p> <p>3 his report.</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question, misstates the testimony.</p> <p>6 A. The -- the two mechanisms --</p> <p>7 I'm sorry, what -- what did you call the</p> <p>8 first one?</p> <p>9 Q. The first mechanism of infection is bacteria</p> <p>10 being blown directly out of the Bair Hugger onto the</p> <p>11 surgical site.</p> <p>12 A. Yes.</p> <p>13 Q. The second mechanism of infection that Dr.</p> <p>14 Samet describes is the Bair Hugger creating convection</p> <p>15 currents in the operating room airflow --</p> <p>16 A. Right. Okay.</p> <p>17 Q. -- that cause bacteria from anywhere in the</p> <p>18 operating room, not just the Bair Hugger device, --</p> <p>19 A. Right.</p> <p>20 Q. -- to enter the surgical field.</p> <p>21 A. Yes.</p> <p>22 Q. Mr. Albrecht's testing did not involve</p> <p>23 mechanism two.</p> <p>24 A. That's correct.</p> <p>25 Q. To the extent that you have opined that</p>

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<p style="text-align: right;">Page 41</p> <p>1 particles are at best an indeterminate outcome of deep</p> <p>2 joint infection, you are relying on Mr. Albrecht's</p> <p>3 testimony; correct?</p> <p>4 A. In part, yes.</p> <p>5 Q. You told me in full. Is there something</p> <p>6 else now that you're relying on to make that</p> <p>7 conclusion?</p> <p>8 A. Well the -- what he --</p> <p>9 As I understand it, what he was looking at</p> <p>10 was particles and without distinguishing exactly what</p> <p>11 those particles were, so what I'm saying, he looked --</p> <p>12 You know, there are particles there, that's</p> <p>13 part of what he shows; some of them may come directly</p> <p>14 from the hose, some of them maybe have been -- involve</p> <p>15 the second -- second mechanism where it disturbed the</p> <p>16 air around it and has particles from that. What I'm</p> <p>17 opining on is that the -- directly measuring bacteria</p> <p>18 or infectious agents on those particles, that's --</p> <p>19 that's what I was referring to.</p> <p>20 Q. But you would agree that Mr. Albrecht's</p> <p>21 testing did not directly relate to causal mechanism</p> <p>22 two. You've already said that.</p> <p>23 MR. GORDON: Object.</p> <p>24 A. Okay. Yes.</p> <p>25 Q. And so your conclusion, which are that</p>	<p style="text-align: right;">Page 43</p> <p>1 would conclude that particles are linked to bacteria.</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. The parti -- I -- I --</p> <p>5 Yeah, I -- I don't under --</p> <p>6 Q. Okay. I'll rephrase.</p> <p>7 Would it help if there was peer-reviewed</p> <p>8 literature which concluded that as the number of</p> <p>9 particles increase, so too do the number of bacteria?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question.</p> <p>12 A. Always?</p> <p>13 Q. In a randomized controlled trial in</p> <p>14 orthopedic surgeries.</p> <p>15 A. So you're analyzing the -- the particles</p> <p>16 that are in the -- on the operating room during --</p> <p>17 during orthopedic surgery --</p> <p>18 Q. Yes.</p> <p>19 A. -- and -- and looking at -- at --</p> <p>20 Yeah. If -- if there were -- if -- if I had</p> <p>21 seen reports of that, I -- I would find that more</p> <p>22 convincing, yes.</p> <p>23 Q. And that would allow you to determine</p> <p>24 whether an increase in particles could be linked to</p> <p>25 bacteria.</p>
<p style="text-align: right;">Page 42</p> <p>1 particles are an indeterminate outcome of deep joint</p> <p>2 infection, relies on Mr. Albrecht's conclusions as to</p> <p>3 causal mechanism number one.</p> <p>4 A. In -- in part, yes. But the --</p> <p>5 To say that what's on the particles, I mean</p> <p>6 that -- that -- I'm -- I'm making that -- that -- that</p> <p>7 claim generally. It's more than just looking at</p> <p>8 whether or not the particles have been dispersed, it's</p> <p>9 looking at what -- what's on those particles and</p> <p>10 analyzing the content of those particles.</p> <p>11 Q. Have you --</p> <p>12 A. And from what I can tell, there was no</p> <p>13 analysis of the chemistry or direct measurements of</p> <p>14 the -- of what if any organ -- any infectious</p> <p>15 organisms were on those particles.</p> <p>16 Q. So would it help you if there were studies</p> <p>17 that linked particle concentration to bacterial</p> <p>18 concentration?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. Are you -- you mean --</p> <p>22 Do you mean any studies or do you mean</p> <p>23 studies particularly related to the Bair Hugger</p> <p>24 device?</p> <p>25 Q. I'm saying peer-reviewed literature that</p>	<p style="text-align: right;">Page 44</p> <p>1 A. It's a possibility. Again, it's -- it's --</p> <p>2 from when --</p> <p>3 When I say "indirect," the direct evidence</p> <p>4 is ultimately the infection. That's the --</p> <p>5 Q. Okay.</p> <p>6 A. That's the event you want to look at and</p> <p>7 that's -- that's the event that's of most interest.</p> <p>8 But the event you're talking about is whether or not</p> <p>9 there's something on the particles.</p> <p>10 Q. So if deep joint infection is the outcome of</p> <p>11 interest, --</p> <p>12 A. Yes.</p> <p>13 Q. -- it would be especially helpful if there</p> <p>14 was an article that linked particles to bacteria, and</p> <p>15 what I mean by that is that the more particles, the</p> <p>16 more bacteria, but also found that the more bacteria,</p> <p>17 the greater risk of infection.</p> <p>18 A. Yes.</p> <p>19 Q. That would be very helpful evidence in</p> <p>20 determining whether the Bair Hugger increases the risk</p> <p>21 of infection.</p> <p>22 A. Well it's -- it's not directly related to</p> <p>23 the Bair Hugger, but it would be -- yeah, it --</p> <p>24 it's -- it's helping to pose -- to understand what the</p> <p>25 potential mechanism might be.</p>

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<p>1 Q. What about studies that have -- that would</p> <p>2 have concluded that the Bair -- Bair Hugger actually</p> <p>3 increases the number of bacteria at the surgical site,</p> <p>4 would that be helpful?</p> <p>5 A. Yes.</p> <p>6 Q. And studies that show that the Bair Hugger</p> <p>7 increases the number of particles at the surgical</p> <p>8 site.</p> <p>9 A. Yes. Compared to, you know, whatever the</p> <p>10 comparison group is, yes.</p> <p>11 Q. Did you review any articles involving the</p> <p>12 subject matter we just discussed, which is the</p> <p>13 relationship of particles to bacteria and bacteria to</p> <p>14 deep joint infection?</p> <p>15 A. That was not really part of my -- my review,</p> <p>16 no.</p> <p>17 Q. So you have not reviewed the article by</p> <p>18 Gregory Stocks; correct?</p> <p>19 A. No.</p> <p>20 Q. You have not reviewed the article by</p> <p>21 Darouiche et al; correct?</p> <p>22 A. Correct.</p> <p>23 Q. You have not reviewed the article by</p> <p>24 Moretti.</p> <p>25 A. Correct.</p>	<p>1 the paragraph beginning, "The purpose of this study</p> <p>2 was to determine whether the density of airborne</p> <p>3 particulates at the surgery site and various behaviors</p> <p>4 of operating room personnel can be used to predict the</p> <p>5 density of viable airborne bacteria (ie, colony-</p> <p>6 forming units (CFU) at the surgery site during hip and</p> <p>7 knee joint arthroplasty?"</p> <p>8 A. Yes.</p> <p>9 Q. This --</p> <p>10 The purpose of this article was to determine</p> <p>11 whether particulates are related to bacteria in</p> <p>12 orthopedic surgery; correct?</p> <p>13 A. Yes.</p> <p>14 Q. If you could turn to the third page of the</p> <p>15 study in the "RESULTS" section on the right-hand</p> <p>16 column in the first full paragraph that begins "Table</p> <p>17 2..." Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. The last sentence of that paragraph states,</p> <p>20 "Neither sex nor surgery type was significantly</p> <p>21 related to the square root CFU/m cubed;" correct?</p> <p>22 I guess it's the second sentence. I</p> <p>23 apologize.</p> <p>24 A. Oh, oh, I -- okay. I was looking at the --</p> <p>25 Q. Do you see the third sentence?</p>
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<p>1 (Exhibit 7 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. SACCHET:</p> <p>4 Q. Doctor, this is an article authored by</p> <p>5 Gregory Stocks; correct?</p> <p>6 A. Yes.</p> <p>7 Q. The title of the article is "Predicting</p> <p>8 bacterial populations based on airborne particulates:</p> <p>9 A study performed in nonlaminar flow operating rooms</p> <p>10 during joint arthroplasty surgery;" correct?</p> <p>11 A. That's the correct title, yes.</p> <p>12 Q. The title involves the same subject matter</p> <p>13 that we have just been discussing, which is the</p> <p>14 relationship of particles to bacteria in orthopedic</p> <p>15 surgeries; correct?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, lack of foundation.</p> <p>18 If you want him to read -- read it so he can</p> <p>19 answer the question --</p> <p>20 MR. SACCHET: I asked if the title reflects</p> <p>21 the subject matter that we have discussed. I said</p> <p>22 nothing about the article itself.</p> <p>23 A. It appears to, yes.</p> <p>24 Q. And if I could turn your attention to the</p> <p>25 bottom right-hand corner of the first page, do you see</p>	<p>1 A. "...nor surgery type..." that's what it</p> <p>2 says.</p> <p>3 Q. Yeah. And the second --</p> <p>4 And the next sentence says, "Surgery</p> <p>5 duration, 5 micron to 9.99 micron particles per meter</p> <p>6 cubed, greater than or equal to 10 micron particles</p> <p>7 count per m cubed and staff count were each</p> <p>8 significantly related (with a p-value of less than</p> <p>9 .05) to the square root of the CFU per meters cubed;"</p> <p>10 correct?</p> <p>11 A. That's what it says, yes.</p> <p>12 Q. Turning to the next page, in the right-hand</p> <p>13 column, the first full paragraph begins with, "The</p> <p>14 finding of a correlation..." Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. It states, "The finding of a correlation</p> <p>17 between the number of 10 micron particles per meter --</p> <p>18 per m cubed and CFU per m cubed at the surgical site</p> <p>19 has several important implications. First, it</p> <p>20 supports airborne parti -- particulate contamination</p> <p>21 of the wound as a source of postoperative infection in</p> <p>22 joint arthroplasty, as emphasized by Edmiston et al."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. And finally on the last page, the last</p>

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<p style="text-align: right;">Page 49</p> <p>1 paragraph of text, do you see where it starts, "We 2 have found...?"</p> <p>3 A. Yes.</p> <p>4 Q. And it relates that, "We have found that the 5 number of airborne particulates greater than 10 6 microns was correlated with the number of CFUs grown 7 from the air sampled within the sterile field 8 approximately 40 centimeters from surgical incision." 9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Do you have any reason to doubt the 12 conclusions of Stocks et al?</p> <p>13 A. I have not --</p> <p>14 This is the first I've -- first I've seen 15 this paper, so I would have to study it and -- to get 16 a better understanding of their methodology and what 17 they had done to -- to reach an opinion on this paper.</p> <p>18 Q. Would it help you if one of 3M's past 19 experts had opined that the methods were good?</p> <p>20 MR. GORDON: Object to the form of the 21 question.</p> <p>22 A. No.</p> <p>23 Q. Do you know Mr. Russ -- Mr. Russell 24 Olmstead, an epidemiologists and infectious -- 25 A. No, I don't know him.</p>	<p style="text-align: right;">Page 51</p> <p>1 A. Yes.</p> <p>2 Q. And the first line says, "Hi Gary: fairly 3 remarkable paper given an ability to present during 4 actual procedures. I had not seen it so thanks for 5 bringing it to my attention. Demonstrates that pre 6 press page is useful place to visit often. It is 7 difficult to get IRB approval for such investigations. 8 I don't know the authors but the methods employed are 9 very good and I like the use of electronic particle 10 counts AND bacterial air sampling. Very helpful 11 picture of what happens in a typical non- 12 unidirectional HVAC design." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Do you have any reason to doubt that the 15 methods in this paper are anything but well designed?</p> <p>16 MR. GORDON: Object to the form of the 17 question, also lack of foundation.</p> <p>18 A. I don't un -- I mean I -- I -- that's -- 19 That's this person's review of it, that's 20 his opinion of it. I agree -- I agree that that's his 21 opinion. I don't have an opinion on it because I have 22 not reviewed it.</p> <p>23 Q. But you have seen that this article has 24 concluded that there is a link between airborne 25 particulates and bacteria; correct?</p>
<p style="text-align: right;">Page 50</p> <p>1 Q. -- disease doctor?</p> <p>2 A. No, I don't know him.</p> <p>3 Q. So you're not aware that he has stated that 4 the methods of Stocks are well done.</p> <p>5 MR. GORDON: Object to the form of the 6 question.</p> <p>7 A. I am not aware of what he -- what he has 8 said about this paper. I'm not familiar with it. 9 (Exhibit 8 was marked for 10 identification.)</p> <p>11 BY MR. SACCHET:</p> <p>12 Q. The subject line of this e-mail is "Stocks 13 Papers;" correct?</p> <p>14 A. Yes.</p> <p>15 Q. In the e-mail at the top we have a statement 16 from Mr. Gary Hansen to a Mr. Russell Olmstead 17 stating, "Could you send me a copy of the older Stocks 18 paper? AJIC does not sell them on line." Do you see 19 that?</p> <p>20 A. Yes.</p> <p>21 Q. And in the e-mail below that there are two 22 paragraphs; correct?</p> <p>23 A. Yes.</p> <p>24 Q. And the text is from Russell Olmstead, do 25 you see that?</p>	<p style="text-align: right;">Page 52</p> <p>1 A. I've --</p> <p>2 You just read me the paragraph, and I agree 3 that you've read them correctly to me.</p> <p>4 Q. And as we established earlier, you said it 5 would be helpful if there was peer-reviewed literature 6 concluding that there was a link between particles and 7 bacteria; correct?</p> <p>8 A. Well it would be helpful if I -- if it 9 was not only peer-reviewed but I had a chance to 10 review it.</p> <p>11 Q. So --</p> <p>12 A. I'm not going to take a peer-reviewed 13 article --</p> <p>14 You know, every peer-reviewed article is 15 not -- is not -- not appro -- not correct, --</p> <p>16 Q. Okay.</p> <p>17 A. -- so I need --</p> <p>18 One needs a chance to actually review the 19 science and digest what -- what was -- the work that 20 was actually done to reach a conclusion.</p> <p>21 Q. So you did not review this article in 22 opining that particles are at most an indeterminate 23 outcome of deep joint infection.</p> <p>24 A. That's correct.</p> <p>25 Q. You also said that it would be helpful if</p>

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<p style="text-align: right;">Page 53</p> <p>1 there were articles that concluded that particles were</p> <p>2 not only related to bacteria but also that bacteria</p> <p>3 was related to deep joint infection; correct? That's</p> <p>4 what you testified to.</p> <p>5 A. Yes.</p> <p>6 Q. Have you reviewed any such articles,</p> <p>7 professor?</p> <p>8 A. No, I haven't. I mean it's -- it's -- this</p> <p>9 is not --</p> <p>10 That particular part of it is not really my</p> <p>11 area.</p> <p>12 Q. So it's not your area, but you concluded</p> <p>13 that particles are at most an indeterminate outcome of</p> <p>14 infection.</p> <p>15 A. I --</p> <p>16 The infection is the ultimate outcome that I</p> <p>17 was interested in in looking at the McGovern paper, so</p> <p>18 it's the occurrence of the infection which is -- which</p> <p>19 is the outcome that I was most interested in. Whether</p> <p>20 there's infectious organisms on particles is basically</p> <p>21 an intermediate step which would be helpful of</p> <p>22 understanding, perhaps, how they got there.</p> <p>23 Q. Okay.</p> <p>24 A. But it's not the outcome that I was</p> <p>25 particularly interested in.</p>	<p style="text-align: right;">Page 55</p> <p>1 either incisional or prosthesis-related surgical site</p> <p>2 infections;" correct?</p> <p>3 A. Yes.</p> <p>4 Q. This was a randomized controlled trial;</p> <p>5 correct?</p> <p>6 A. That's what it says.</p> <p>7 Q. Randomized controlled trials are first-tier</p> <p>8 scientific evidence; correct?</p> <p>9 A. They can be, yes.</p> <p>10 Q. Are there other types of studies that are</p> <p>11 given more weight than RCTs?</p> <p>12 A. In general, they're -- they're given the</p> <p>13 most weight, yes, if they're well done.</p> <p>14 Q. If we could turn to page six, and you'll see</p> <p>15 the pages are listed on the top of the paper, under</p> <p>16 the header "CFU and Particulate Densities and</p> <p>17 Infection," do you see that heading?</p> <p>18 A. Yes.</p> <p>19 Q. It states, "CFU density at incision sites</p> <p>20 was significantly related to incidence of implant</p> <p>21 infections (with a p-value of .021), but not of</p> <p>22 incisional infections (with a p-value of .687). Every</p> <p>23 10 CFU per m cubed increase in median CFU denies</p> <p>24 approximately doubled the probability of implant</p> <p>25 infection (Figure 4). CFU density was positively</p>
<p style="text-align: right;">Page 54</p> <p>1 Q. So let's look at this paper which --</p> <p>2 THE REPORTER: Just a moment.</p> <p>3 (Exhibit 9 was marked for</p> <p>4 identification.)</p> <p>5 BY MR. SACCHET:</p> <p>6 Q. The title of this article is the</p> <p>7 "Association of Airborne Microorganisms in the</p> <p>8 Operating Room With Implant Infections: A Randomized</p> <p>9 Controlled Trial;" correct?</p> <p>10 A. Yes.</p> <p>11 Q. The title of this article relates to the</p> <p>12 relationship of airborne microorganisms to infection;</p> <p>13 correct?</p> <p>14 A. That's what the title is, yes.</p> <p>15 Q. That is the subject matter by which you</p> <p>16 testified one minute ago that it would be helpful to</p> <p>17 review to determine whether bacteria are related to</p> <p>18 the outcome of interest, deep joint infection;</p> <p>19 correct?</p> <p>20 A. That would be helpful for under -- to</p> <p>21 perhaps get an understanding of the mechanisms, yes.</p> <p>22 Q. The objective of the paper was to, quote,</p> <p>23 "To evaluate the association of airborne colony-</p> <p>24 forming units (CFU) at incision sites during</p> <p>25 implantation of prostheses with the incidence of</p>	<p style="text-align: right;">Page 56</p> <p>1 related to total particulate density (with a p-value</p> <p>2 of less than .001) in the control group, indicating</p> <p>3 that airborne particle counts may be used as a proxy</p> <p>4 for ambient CFU density." Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. On page eight of this study, very last</p> <p>7 paragraph, do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. "In conclusion, our results indicate that</p> <p>10 CFU contamination of air at the incision site is a</p> <p>11 risk factor for implant but not incisional infections.</p> <p>12 CFU contamination is related to the particulate</p> <p>13 density in the air at the incision site, and both CFU</p> <p>14 and particulate density are a function of the number</p> <p>15 of people in the operating room. Limiting airborne</p> <p>16 CFU contamination at the incision site can be expected</p> <p>17 to lower implant infection risk."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. You have no reason to doubt that conclusion;</p> <p>21 do you?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, lack of foundation.</p> <p>24 A. That conclusion would be based on the -- the</p> <p>25 whole study, and you've just given me this study, and</p>

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<p style="text-align: right;">Page 57</p> <p>1 I haven't had a chance to really study this paper, so 2 I would -- I would need to study the paper in order 3 to -- to have an opinion on that conclusion. 4 Q. You didn't study the paper, but you did 5 conclude that particles are at best an indeterminate 6 outcome of infection; correct? 7 MR. GORDON: Object to the form of the 8 question. 9 A. I -- I concluded, as I've -- I've explained 10 the reason my -- 11 What I meant when I said that is that that 12 was a diff -- an intermediate outcome. I mean what 13 you have read to me does not -- 14 I didn't see that the Bair Hugger was 15 involved with this. Is that correct? 16 Q. The Bair Hugger was not involved in this 17 study. 18 A. Okay. 19 Q. Would it help you if I showed you studies -- 20 A. If you -- 21 If this study had used the Bair Hugger, that 22 would help. 23 Q. Would it help you if I showed you studies 24 showing the Bair Hugger increasing particles or 25 increasing bacteria?</p>	<p style="text-align: right;">Page 59</p> <p>1 A. That appears to be from the limited reading 2 that -- that we've just done. 3 Q. You have seen that it's a randomized 4 controlled trial. 5 A. I've seen it described there. I have not 6 reviewed exactly what they did, how they did the 7 randomization. 8 Q. And this paper also concludes that the 9 number of bacteria increase -- as the bacteria 10 increases, that increases the risk of DJI, deep joint 11 infection; correct? 12 A. That is their -- that is their conclusion, 13 yes. 14 Q. If this paper did not involve the Bair 15 Hugger, would it help you to see studies that conclude 16 that the Bair Hugger increases particles? 17 A. It would -- it would help to see that it 18 increases particles and it increases the -- the risk 19 of infection. 20 Q. If this paper establishes a link between 21 particles, bacteria and infection, -- 22 A. Yes. 23 Q. -- and the Bair Hugger increases particles, 24 is it your testimony that one cannot also conclude 25 that the Bair Hugger increases bacteria?</p>
<p style="text-align: right;">Page 58</p> <p>1 MR. GORDON: Object to the form of the 2 question, compound. 3 A. Well which -- which -- 4 What is the outcome that you're -- you're 5 showing me? 6 Q. So we have a study here, and you would agree 7 that it has concluded that particles have a 8 relationship to bacteria and bacteria has a 9 relationship to deep joint infection; correct? 10 MR. GORDON: Are you talking about Exhibit 11 8? 12 MR. SACCHET: I'm talking about Exhibit -- 13 A. Exhibit 9? 14 MR. SACCHET: -- 9. 15 A. What? 16 Q. This paper concludes -- 17 A. This one is 9. 18 Q. Darouiche, Exhibit 9. 19 A. Yeah, okay. 20 Q. -- that the amount of particles is related 21 to the amount of bacteria; correct? 22 A. That's what they -- that's this paper -- 23 that's -- 24 That's what they found in -- in this trial. 25 Q. Yes.</p>	<p style="text-align: right;">Page 60</p> <p>1 MR. GORDON: Object to the form of the 2 question, lack of foundation, incomplete hypothetical. 3 Q. It's a simple syllogism: Premise one, 4 particles relate to bacteria; premise two, bacteria 5 relates to deep joint infection. Q.E.D., if Bair 6 Hugger increases particles, does it increase bacteria? 7 MR. GORDON: Object to the form of the 8 question, lack of foundation, it's an incomplete 9 hypothetical. 10 A. You haven't -- you -- you haven't shown the 11 whole -- whole scenario. 12 Q. What's the whole scenario? 13 A. Well that -- that you used the Bair -- used 14 the Bair Hugger -- 15 Q. Yeah. 16 A. -- and that in turn increases your risk 17 of -- the risk of infection. 18 Q. So you would only conclude that the Bair 19 Hugger increases infection if there was a study 20 showing the Bair Hugger increases the risk of 21 infection. 22 MR. GORDON: Object to the form of the 23 question. 24 A. I would -- I would want to see a well- 25 controlled study that showed that use of the Bair</p>

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<p style="text-align: right;">Page 61</p> <p>1 Hugger during surgery increased risk of -- of -- of 2 infection. 3 Q. Epidemiology considers more than evidence 4 that draws a unidirectional link between a variable 5 and an outcome; correct? 6 MR. GORDON: Object to the form of the 7 question. 8 A. Yeah. I don't understand the question. 9 Q. Part of epidemiology considers the mechanism 10 of infection; correct? 11 A. That's one aspect of interest, yes. 12 Q. That relates to the coherency of whether a 13 cause increases an outcome; correct? 14 A. That's one of the considerations, is the 15 mech -- is -- is the mechanism. 16 Q. And when you consider a mechanism, you can 17 consider intermediate outcomes that lend biological 18 plausibility to causal inference; correct? 19 A. Well intermediate outcomes very often 20 have -- have -- have not worked out in ep -- in 21 epidemiological studies. Sometimes -- sometimes -- 22 Q. I'm going to -- I'm going to interrupt you 23 and mover to strike. The question is -- 24 MR. GORDON: No. Let him answer the 25 question, then you can move to strike if you don't</p>	<p style="text-align: right;">Page 63</p> <p>1 dose/response relationship. A dose/response 2 relationship would be -- would be one important thing 3 to look at. 4 Q. What -- 5 In your view what is -- what is the material 6 dose with respect to whether the Bair Hugger increases 7 infection? 8 MR. GORDON: Object to the form of the 9 question, lack of foundation. 10 A. I don't -- I don't recall seeing in any of 11 the -- the -- the -- for example, the McGovern study, 12 anything on dose of Bair Hugger. You either use it or 13 you don't. It's a binary -- 14 Q. What causes infection? 15 MR. GORDON: Object -- same objections. 16 A. What causes -- 17 Q. What -- what -- what thing leads to an 18 infection? Particles? Bacteria? What? 19 MR. GORDON: Object. 20 A. Bacteria. 21 Q. So is bacteria the dose, because the more 22 bacteria you have, the greater incidence of deep joint 23 infection? 24 MR. GORDON: Object to the form of the 25 question, lack of foundation.</p>
<p style="text-align: right;">Page 62</p> <p>1 like it, but don't cut -- don't cut him off during 2 the -- his answer. 3 A. I mean there -- there are many -- there are 4 many studies that look at intermediate outcomes 5 that -- 6 Q. Okay. 7 A. -- that you find an association with 8 intermediate outcomes, but then the main one of 9 interest, which is the primary -- primary point, is -- 10 is not in fact demonstrated. And it -- and it could 11 be due to a number of things; it may be that you have 12 the wrong idea of what the actual mechanism is. 13 Q. In your view, what is the dose at issue in 14 this litigation? 15 MR. GORDON: Object to the form of the 16 question, lack of foundation. 17 A. Dose. 18 Q. Dose is one of the criteria for determining 19 causal inference; correct? 20 A. One of the things that's often of interest 21 is -- is not a -- a particular dose. 22 What dose do you have in mind? I didn't -- 23 Q. As something increases, an outcome could 24 increase. 25 A. Okay. That -- so that would be a</p>	<p style="text-align: right;">Page 64</p> <p>1 MR. SACCHET: We've just reviewed a study on 2 the topic, so there is foundation. 3 A. But -- 4 MR. GORDON: I mean -- 5 A. -- there's no evidence of what the dose -- 6 the dose of bacteria is that's coming from that -- 7 from the Bair Hugger. 8 Q. If the Bair Hugger increases the amount of 9 bacteria -- 10 A. But you're not measuring the dose. 11 Q. If it is found that the Bair Hugger 12 increases the amount of bacteria -- 13 A. Well the dose/response relationship is that 14 you measure different doses and that affects your 15 risk. 16 Q. Would it help you if there were -- 17 A. No one has measured the dose -- the dose of 18 bacteria that's come -- that's come from the Bair 19 Hugger. 20 Q. Do you know that a single bacterium can 21 cause a deep joint infection? 22 A. Yes. 23 Q. So does dose matter if the more bacteria you 24 have and that one bacteria can cause an infection? 25 MR. GORDON: Object to form. Object to the</p>

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<p>1 form of the question, lack of foundation.</p> <p>2 Q. If -- if one bacteria can cause an infection</p> <p>3 and the more bacteria that you have increases the risk</p> <p>4 of infection, it stands to reason that the</p> <p>5 dose/response relationship as to how much the Bair</p> <p>6 Hugger might produce in -- in terms of bacteria is not</p> <p>7 the relevant question.</p> <p>8 MR. GORDON: Object to form, also -- also</p> <p>9 lack of foundation.</p> <p>10 A. I mean you're -- you're not --</p> <p>11 There's no data that you're showing me</p> <p>12 that -- that relates -- that I have seen --</p> <p>13 Q. Yeah.</p> <p>14 A. -- related to the Bair Hugger --</p> <p>15 Q. Okay.</p> <p>16 A. -- that indicates the dose of bacteria that</p> <p>17 each of these patients was exposed to.</p> <p>18 Q. Would a study showing that the Bair Hugger</p> <p>19 increases the amount of bacteria at the surgical site</p> <p>20 help you?</p> <p>21 A. You -- you --</p> <p>22 To establish a dose/response relationship,</p> <p>23 you need to know what the dose is.</p> <p>24 Q. So the only way that you would draw any</p> <p>25 inference about whether the number of bacteria from</p>	<p>1 (Exhibit 10 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. SACCHET:</p> <p>4 Q. Have you seen this document before,</p> <p>5 Professor Holford?</p> <p>6 A. No, I have not.</p> <p>7 Q. The title of the document is the</p> <p>8 "Proceedings of the International Consensus Meeting on</p> <p>9 Periprosthetic Joint Infection;" correct?</p> <p>10 A. Yes.</p> <p>11 Q. Do you know who Javad Parvizi is?</p> <p>12 A. No, I do not.</p> <p>13 Q. So you don't know that he is a consultant</p> <p>14 for 3M?</p> <p>15 A. No, I don't.</p> <p>16 Q. Okay. If you turn to page six, do you see</p> <p>17 the 3M logo?</p> <p>18 A. Yes.</p> <p>19 Q. And above that we see the text "Platinum</p> <p>20 Sponsor;" correct?</p> <p>21 A. Yes.</p> <p>22 Q. So 3M was a platinum sponsor of this</p> <p>23 consensus; correct?</p> <p>24 A. Apparently.</p> <p>25 Q. The next page is page 114.</p>
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<p>1 the Bair Hugger increases the risk of infection is if</p> <p>2 you knew the dose/response relationship?</p> <p>3 MR. GORDON: Object to the form of the</p> <p>4 question.</p> <p>5 A. You're the one that raised the issue of</p> <p>6 there being a dose/response relationship.</p> <p>7 Q. And my question is: What is the dose at</p> <p>8 issue? Bacteria?</p> <p>9 A. I guess --</p> <p>10 Well I don't know. You're the one that</p> <p>11 raised it. I haven't -- I've -- as I've -- as I've</p> <p>12 said, I have not seen anything in these studies that</p> <p>13 measures dose. It could be the num -- the level of</p> <p>14 bacteria, it could be how long you were in surgery, it</p> <p>15 could be, you know, how -- I don't know if there's</p> <p>16 different settings of these -- of these -- on -- on</p> <p>17 the Bair Hugger, but I mean there are -- or -- or for</p> <p>18 that matter any heating -- warming device, so it's --</p> <p>19 Those would be some measurements of -- of</p> <p>20 dose.</p> <p>21 Q. Okay.</p> <p>22 A. And these studies did not do that.</p> <p>23 Q. Okay.</p> <p>24 MR. SACCHET: We're going to pass you what</p> <p>25 will be marked as Exhibit 10.</p>	<p>1 MR. GORDON: Counsel, is there --</p> <p>2 Where is page seven through 113?</p> <p>3 MR. SACCHET: They are not included.</p> <p>4 MR. GORDON: Well I'm going to object to</p> <p>5 this document on the grounds of completeness.</p> <p>6 MR. SACCHET: That's fine.</p> <p>7 Q. Page 114 is entitled "Workgroup 4;" correct?</p> <p>8 A. Yes.</p> <p>9 Q. On the operating room -- "Operative</p> <p>10 Environment;" correct?</p> <p>11 A. Yes.</p> <p>12 Q. And beneath that we see numerous</p> <p>13 delegates -- delegates, all of whom have M.D.s;</p> <p>14 correct?</p> <p>15 A. They seem to, yes.</p> <p>16 Q. Okay. On page 115, question one states, "Do</p> <p>17 numbers of bacteria arriving in the surgical wound</p> <p>18 correlate directly with probability of SSI?" Do you</p> <p>19 see that?</p> <p>20 A. Yes.</p> <p>21 Q. And the consensus statement reads, "We</p> <p>22 recognize that the probability of surgical site</p> <p>23 infection correlates directly with the quantity of</p> <p>24 bacteria that reach the wound. Accordingly we support</p> <p>25 strategies to lower particulate and bacterial counts</p>

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<p style="text-align: right;">Page 69</p> <p>1 at surgical wounds.</p> <p>2 "Delegate Vote: Agree: 97 percent, (Strong</p> <p>3 consensus)."</p> <p>4 Do you see that, professor?</p> <p>5 A. Yes, I do.</p> <p>6 Q. Do you have any reason to doubt the</p> <p>7 consensus statement of these medical doctors?</p> <p>8 MR. GORDON: Object to the form of the</p> <p>9 question.</p> <p>10 A. I -- I mean that's their opinion. That's --</p> <p>11 Yes.</p> <p>12 Q. And this opinion states that the number of</p> <p>13 bacteria at the surgical site relates to the incidence</p> <p>14 of surgical-site infection; correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Does that explain that the number of</p> <p>17 bacteria could be viewed as the dose at issue with</p> <p>18 respect to surgical-site infection?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question, also lack of foundation.</p> <p>21 A. The -- the -- the problem I -- I --</p> <p>22 I mean I'm not sure what connection you're</p> <p>23 looking at. As the statement is --</p> <p>24 Q. Okay.</p> <p>25 A. -- as -- if the --</p>	<p style="text-align: right;">Page 71</p> <p>1 It's not just particles, they're talking</p> <p>2 about bacteria. Right?</p> <p>3 Q. The relationship of part --</p> <p>4 A. Do the -- do the number of bacteria in the</p> <p>5 operating room correlate directly with the probability</p> <p>6 of surgical-site infection, so it's -- you --</p> <p>7 I think you stated the question as</p> <p>8 "particles."</p> <p>9 Q. And it says there should be particular</p> <p>10 attention to airborne particles; correct?</p> <p>11 A. Where are you reading?</p> <p>12 Q. From the consensus statement at the top of</p> <p>13 page 116.</p> <p>14 A. It's referring again to the bacterial</p> <p>15 particles.</p> <p>16 Q. And it says, "The focus of our</p> <p>17 recommendation is to reduce the volume of bacteria in</p> <p>18 the operating room with particular attention to</p> <p>19 airborne particles;" correct?</p> <p>20 A. Well, but the particles that they're</p> <p>21 referring to are airborne particulate bacteria.</p> <p>22 Q. Okay. Let's look at the justification,</p> <p>23 which is the paragraph below that. The third</p> <p>24 statement begins with "Bacteria can be considered..."</p> <p>25 Do you see that?</p>
<p style="text-align: right;">Page 70</p> <p>1 If you have different levels of -- of</p> <p>2 bacteria at the surgical site, you will affect the</p> <p>3 risk.</p> <p>4 Q. Uh-huh. And the more bacteria at the</p> <p>5 surgical site, the increased risk of infection.</p> <p>6 A. That's -- that's what they're -- they're</p> <p>7 concluding, yes.</p> <p>8 Q. Okay. And question two says, "Do numbers of</p> <p>9 bacteria in the operating room environment correlate</p> <p>10 directly with the probability of surgical site</p> <p>11 infection?" And the consensus on that states, "We</p> <p>12 recognize that airborne particulate bacteria are a</p> <p>13 major source of contamination in the operating room</p> <p>14 environment and that bacteria shed by personnel are</p> <p>15 the predominant source of these particles. The focus</p> <p>16 of our recommendation is to reduce the volume of</p> <p>17 bacteria in the operating room with particular</p> <p>18 attention to airborne particles."</p> <p>19 A. Okay.</p> <p>20 Q. This consensus draws a relationship between</p> <p>21 bacteria and particles; correct?</p> <p>22 A. Yes.</p> <p>23 Q. And 93 percent of the delegates agreed to</p> <p>24 that link.</p> <p>25 A. Well they're --</p>	<p style="text-align: right;">Page 72</p> <p>1 A. The third --</p> <p>2 Q. The third sentence. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. "Bacteria can be considered as part of the</p> <p>5 total mass of particulates in the air. Some studies</p> <p>6 have suggested that the airborne parti -- particulate</p> <p>7 count should be considered as a potential surrogate</p> <p>8 for airborne microbial density. Others have found</p> <p>9 correlation between the number of particles larger</p> <p>10 than 10 micrometers with a density of viable bacteria</p> <p>11 at the surgery measured by colony-forming units." Do</p> <p>12 you see that?</p> <p>13 A. Yes.</p> <p>14 Q. So the justification for the consensus</p> <p>15 statement involves the relationship between particles</p> <p>16 and bacteria.</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, lack of foundation.</p> <p>19 A. I mean there again, the --</p> <p>20 I don't think the intent of the statement is</p> <p>21 any old particle. They're interested in particles</p> <p>22 that have bacteria on them.</p> <p>23 Q. I'll read the sentence again.</p> <p>24 A. Well that's what this sentence is, but I</p> <p>25 mean this is what the question is.</p>

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<p style="text-align: right;">Page 73</p> <p>1 Q. The justification for the answer draws a</p> <p>2 link between airborne particles and bacteria; correct?</p> <p>3 A. There --</p> <p>4 Yes, they are saying there is a</p> <p>5 relationship.</p> <p>6 Q. And you have --</p> <p>7 A. There often is a relationship.</p> <p>8 Q. Okay.</p> <p>9 A. That's what they're saying.</p> <p>10 Q. You have no reason to doubt that</p> <p>11 relationship; correct?</p> <p>12 A. But the --</p> <p>13 It depends on what the -- what the</p> <p>14 conditions are in that particular operating room.</p> <p>15 Q. You have no expertise in airborne particles</p> <p>16 is your testimony from earlier this morning.</p> <p>17 A. Okay. So I mean --</p> <p>18 So I don't understand your question.</p> <p>19 Q. So --</p> <p>20 A. If you're saying I don't --</p> <p>21 Q. You have a reason to doubt the conclusion</p> <p>22 even though you don't have expertise in the subject</p> <p>23 matter is my point.</p> <p>24 A. I'm not --</p> <p>25 MR. GORDON: Object to the form of the</p>	<p style="text-align: right;">Page 75</p> <p>1 A. There are --</p> <p>2 Exactly.</p> <p>3 Q. So you would agree in some circumstances --</p> <p>4 A. In some circumstances, yes.</p> <p>5 Q. -- there is a relationship between particle</p> <p>6 load and bacterial load.</p> <p>7 A. In some circumstances.</p> <p>8 Q. And in some circumstances the relationship</p> <p>9 between bacterial load also relates to the increased</p> <p>10 risk of infection; correct?</p> <p>11 A. Yes.</p> <p>12 Q. Are you aware that the Bair Hugger increases</p> <p>13 particles in the operating room?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. I'm -- I'm aware that -- that some of</p> <p>17 the -- some of the studies seem to suggest that</p> <p>18 there -- that there is a -- an increase.</p> <p>19 Q. I notice that you used the word "some" in</p> <p>20 your report as well. That's true; correct?</p> <p>21 A. I don't recall what I -- exactly what I --</p> <p>22 my wording was.</p> <p>23 Q. But your testimony today is that some</p> <p>24 studies show an increase in particulate load over the</p> <p>25 surgical site.</p>
<p style="text-align: right;">Page 74</p> <p>1 question.</p> <p>2 A. I'm not -- I'm -- I'm not dis -- disputing</p> <p>3 what I think they are saying, --</p> <p>4 Q. Okay.</p> <p>5 A. -- which is that -- relates, again, to the</p> <p>6 particles and what is -- what those particles are.</p> <p>7 Q. So when they say there is a correlation</p> <p>8 between the number of particulates with a density of</p> <p>9 viable bacteria, you're interpreting that statement to</p> <p>10 mean that those particles already are bacteria?</p> <p>11 A. If you're in an environment that is somehow</p> <p>12 spraying out part -- particles that are sterile, are</p> <p>13 you -- are you going to use this -- are you using</p> <p>14 this -- their statement here that you're increase --</p> <p>15 you are at increased risk of infection? Is that what</p> <p>16 you're arguing?</p> <p>17 Q. If there is a correlation between the number</p> <p>18 of particles and bacteria is what it says.</p> <p>19 A. From the circumstances that I've described,</p> <p>20 there's not going to be a correlation.</p> <p>21 Q. That may be very well in some circumstances,</p> <p>22 but --</p> <p>23 A. Exactly.</p> <p>24 Q. -- it varies in other circumstances</p> <p>25 according to the consensus statement.</p>	<p style="text-align: right;">Page 76</p> <p>1 A. There have been some studies, yes.</p> <p>2 Q. And some can include all as a logical</p> <p>3 matter; correct?</p> <p>4 A. Some can --</p> <p>5 Q. Some can be all.</p> <p>6 A. All studies have found this?</p> <p>7 Q. I'm just saying it's -- there's --</p> <p>8 There's no point in arguing over the</p> <p>9 semantics, but have you read 3M's -- the deposition of</p> <p>10 3M's corporate representative in this litigation?</p> <p>11 A. No, I have not.</p> <p>12 Q. You have not. So you're not aware that the</p> <p>13 corporate representative for 3M testified that every</p> <p>14 single study indicates that the Bair Hugger increases</p> <p>15 the particle count over the surgical field?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence, lack of</p> <p>18 foundation.</p> <p>19 A. I -- I have not seen that. I hadn't -- had</p> <p>20 not seen that -- that testimony, so I --</p> <p>21 I had not seen that statement.</p> <p>22 MR. GORDON: Are we reaching a point where</p> <p>23 we can take a quick break?</p> <p>24 MR. SACCHET: In a little bit, yeah. I'll</p> <p>25 try to move through this.</p>

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<p>1 (Exhibit 11 was marked for 2 identification.) 3 BY MR. SACCHET: 4 Q. This on the cover page has been denoted as 5 the deposition of Albert Van Duren. Do you see that, 6 Dr. Holford? 7 A. Yes. 8 Q. Okay. And turning to the back side of the 9 paper, there are lines of testimony; correct? Do you 10 see page 258 internal? 11 A. Yes. 12 Q. Do you see lines five through 10? 13 A. Yes. 14 Q. Line five states: "Based on the data that 15 we have today, including the study funded by 3M as 16 well as other studies, every single study indicates 17 that the Bair Hugger increases the particle count over 18 the sterile field; correct?" 19 "Answer: In absolute numbers, yes. 20 "Question: Okay. And you have no internal 21 study to refute that; correct? 22 "No, we don't." 23 A. Okay. 24 Q. Does this clarify your position as to 25 whether some studies have shown an increase in</p>	<p>1 Q. Is a bubble a particle? 2 A. The bubble part of it was not taking place 3 during -- during surgery. 4 Q. It was a simulated surgery; correct? 5 A. It was simulated. 6 Q. Right. 7 A. It was not the actual surgery. 8 Q. Fair enough. But they did find an increase 9 of bubbles over the surgical site from the use of the 10 Bair Hugger compared to a conductive warming device. 11 A. Yes. I read that part of it, yes. 12 Q. You reviewed the Legg studies; correct? 13 A. No, I don't think I did. 14 Q. You didn't. So you're not aware that the 15 2013 Legg study found a one-thousand-times increase in 16 particles over the surgical site from the use of the 17 Bair Hugger compared to a radiant warming device. 18 A. I'm not familiar with that study, no. 19 Q. You're not aware that the 2012 Legg study 20 also found a statistically significant increase in 21 particles over the surgical site after use of the Bair 22 Hugger device. 23 A. I am not familiar with that one. 24 Q. Have you reviewed the Belani study? 25 A. No.</p>
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<p>1 particles over the surgical site as a result of the 2 Bair Hugger? 3 MR. GORDON: Object to the form of the 4 question, lack of foundation. 5 A. There are some -- there are some studies. 6 Q. Does this -- 7 A. I don't think -- 8 Q. -- testimony from 3M use the word "all" or 9 "some?" 10 MR. GORDON: Object to the form of the 11 question, lacks foundation. 12 A. I mean I've -- I've -- what -- what you're 13 showing me is just this one -- one statement. I don't 14 know what all went before this. My impression from 15 what you just read is that when they say "all," 16 there's a whole set of studies that came before this 17 and the "all" of refers to those. 18 Q. Do you know any studies that have not found 19 an increase in particles over the surgical site after 20 use of the Bair Hugger? 21 A. No, I don't. 22 Q. You reviewed the McGovern study; correct? 23 A. Yes. I don't recall that the -- I don't 24 recall the -- the McGovern study actually measuring 25 particles over the surgical -- over the surgical site.</p>	<p>1 Q. You're not aware that the Belani study found 2 that there was an increase in bubbles over the 3 surgical site after the use of the Bair Hugger 4 compared to a conductive warming device. 5 A. I'm not familiar with that, no. 6 Q. Have you reviewed the Sessler study? 7 A. No, I have not. 8 Q. You're not aware that the Sessler study also 9 found an increase in particles over the surgical site 10 from the use of the Bair Hugger when it was on versus 11 when it was off. 12 MR. GORDON: Object to the form of the 13 question, assumes facts not in evidence, misstates the 14 testimony. 15 A. I'm not familiar with the -- with the -- 16 with the findings of that study, no. 17 Q. Have you reviewed any studies that show that 18 the Bair Hugger increases the amount of bacteria over 19 the surgical site? 20 A. No, I'm not familiar with that. 21 MR. SACCHET: Just maybe five more minutes. 22 (Exhibit 12 was marked for 23 identification.) 24 BY MR. SACCHET: 25 Q. The title of this article, professor, is</p>

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<p style="text-align: right;">Page 81</p> <p>1 "Convection warmers -- a possible source of 2 contamination in laminar airflow operating theatres?" 3 Correct? 4 A. Yes. 5 Q. Do you see in the summary in the second line 6 from the bottom, it starts, "This study" -- or I 7 apologize. "A further small rise..." Do you see the 8 beginning of that sentence, third-to-the-last 9 statement in the abstract? 10 A. Yes. 11 Q. "A small -- A further small rise is seen 12 after the convection heaters were turned on when 13 applied to patients. This study showed that use of 14 warm air convection heaters on patients produced a 15 small increase in the number of colony forming units 16 in ultra-clean air theatres but the levels were 17 unlikely to have clinical significance." Do you see 18 that? 19 A. Yes. 20 Q. So this study, based on the summary -- and I 21 understand you have not reviewed it in whole -- does 22 conclude that there was as small increase in bacteria 23 from a convection warmer. 24 MR. GORDON: Object to the form of the 25 question, --</p>	<p style="text-align: right;">Page 83</p> <p>1 be statistically significant. It may not be the only 2 thing you consider, but it's certainly an -- an 3 important part of it. 4 Q. But for clinical significance, it's not 5 necessary to have statistical significance. 6 A. Oh, I -- I'm -- no, I -- 7 Q. Not necessary. 8 A. I think it would be important to have 9 statistical significance to say that it's 10 clinically -- clinically important. 11 Q. Do you disagree with the recent statement of 12 The American Statistical Association that concludes 13 that clinical significance is not determined by 14 statistical significance? 15 MR. GORDON: Object to the form of the 16 question. 17 A. I'm not familiar with the particular 18 statement that you're saying, but I mean I think 19 it's -- I think we're, again, quibbling about -- 20 I mean I -- I doubt that they're saying 21 that -- that when looking at a clinical effect, you 22 don't -- you're not interested in whether or not the 23 association of the study was statistically 24 significant. 25 Q. Well I'm not -- I'm not limiting the</p>
<p style="text-align: right;">Page 82</p> <p>1 A. That was -- 2 MR. GORDON: -- lack of foundation. 3 A. That was unlikely to have clinical 4 significance. 5 Q. Okay. And would it help if there were a 6 study that showed that there was a statistically 7 significant difference in terms of the amount of 8 bacteria produced by the Bair Hugger when it was on 9 versus off? 10 MR. GORDON: Object to the form of the 11 question, lack of foundation, incomplete hypothetical. 12 A. Well I mean statistical significance is 13 not -- well it's -- it's part of what -- what would be 14 convincing, but it also has to do with the magnitude 15 of what that effect would be, of whether or not it 16 would have a clinical -- you know, be clinically 17 important. 18 Q. Statistical significance is not the same as 19 clinical significance; correct? 20 A. Correct. 21 Q. And epidemiology does not hinge on whether a 22 result is statistically significant or not; correct? 23 A. Well the -- the -- for -- 24 To definitely demonstrate a -- an 25 epidemiological effect, you'd want the association to</p>	<p style="text-align: right;">Page 84</p> <p>1 question to whether you're interested in it. 2 Whether something is statistically 3 significant or not is a different question than 4 whether it's clinically significant. 5 A. It is a different question. 6 Q. Okay. 7 A. Yes. 8 Q. Statistical significance is not equivalent 9 to scientific, human, or economic significance; 10 correct? 11 A. Correct. 12 Q. One of the reasons why you say the McGovern 13 study has no import with respect to the relationship 14 between the Bair Hugger and deep joint infection is 15 that, based on using Fisher's exact test instead of 16 chi-squared and based on Albrecht's Exhibit 10, the 17 p-value is .0507; correct? 18 MR. GORDON: Object to the form of the 19 question. 20 A. I think that's what I -- what I found in my 21 analysis, yes. 22 Q. And the statement of the ASA is that 23 statistical significance is not equivalent to 24 scientific, human, or economic significance; correct? 25 A. Yes.</p>

21 (Pages 81 to 84)

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<p style="text-align: right;">Page 85</p> <p>1 MR. SACCHET: Okay. We'll take a break. 2 (Recess taken.) 3 BY MR. SACCHET: 4 Q. Dr. Holford, if we could turn back to your 5 curriculum vitae, which has been marked as Exhibit 2. 6 I don't think you'll need it to answer these 7 questions, but in case you do, there it is. 8 You are a fellow of The American College of 9 Epidemiology; correct? 10 A. Yes. 11 Q. Does your membership in the college reflect 12 your expertise in that subject matter? 13 A. Yes. 14 Q. And that subject matter is the incidence of 15 disease in certain populations; correct? 16 A. Well it's -- it's more than just the 17 incidence, it's the -- it's a -- a lot of studies of 18 etiology of disease. 19 Q. Okay. How many members are there in the 20 college, do you know? 21 A. No, I don't. 22 Q. Okay. The other members are presumably 23 experts in the field as well; correct? 24 A. In different aspects of epidemiology, yes. 25 Q. What does it take for one to become the</p>	<p style="text-align: right;">Page 87</p> <p>1 A. That's correct. 2 Q. Are you aware that Professor Nachtsheim is 3 also a member of the association? 4 A. I didn't know that, but -- 5 Q. You know that Professor Nachtsheim was one 6 of the authors of the McGovern study; correct? 7 A. Yes. 8 Q. So you have no doubt that Professor 9 Nachtsheim is an expert in the field of statistics. 10 A. Yes, I'm sure he'd have some expertise in 11 that. 12 Q. You did not review Professor Nachtsheim's 13 deposition; correct? 14 A. No, I did not. 15 Q. So you do not know anything about Dr. 16 Samet's testimony regarding the statistical methods 17 that were employed in the McGovern study; correct? 18 MR. GORDON: Did you mean to say "Samet?" 19 MR. SACCHET: No. 20 MR. GORDON: You just said "Samet." 21 MR. SACCHET: Oh. Thanks, Mr. Gordon. 22 Q. You're not aware of what Professor 23 Nachtsheim testified about the statistical methods 24 used in the McGovern study; correct? 25 A. I -- I --</p>
<p style="text-align: right;">Page 86</p> <p>1 president of the college? 2 A. You have to run for election and be -- get 3 the most votes. 4 Q. Have you voted in such an election? 5 A. I -- I think I voted, yes. 6 Q. What are your criteria for voting someone to 7 be president? 8 A. My view of their scientific standing. 9 Q. So the president would have sound scientific 10 standing in your view. 11 A. Yes. Oh, yeah. 12 Q. You're aware that Dr. Samet was elected 13 president of the college in 1999; correct? 14 A. Yes. 15 Q. In that regard you review -- you view Dr. 16 Samet as an expert in epidemiology. 17 A. I do. 18 Q. You're also a member of The American College 19 of Statistics; correct? 20 A. Well it's The American Statistical 21 Association. 22 Q. Okay. Thanks for the clarification. 23 And I assume the same holds true: if you're 24 a member of that association, presumably you're an 25 expert in some matter in statistics; correct?</p>	<p style="text-align: right;">Page 88</p> <p>1 My knowledge of what was -- statistical 2 methods were used is what's -- is what was in the 3 McGovern paper. 4 Q. So the Nachtsheim deposition transcript 5 played no role in your opinion that you provided in 6 your expert report; correct? 7 A. Correct. 8 Q. You're not aware of whether Professor 9 Nachtsheim provided a justification for using 10 chi-squared instead of Fisher's exact; are you? 11 A. No, I'm not. 12 Q. You're not aware of whether Professor 13 Nachtsheim continues to stand by the calculations 14 that were made in the McGovern study; correct? 15 A. I -- I have no idea what -- what his 16 opinions are. 17 Q. You're not aware of whether Professor 18 Nachtsheim commented on the accuracy of Albrecht 19 Exhibit 10 or McGovern Exhibit 16; correct? 20 A. Correct. 21 Q. I apologize if I've already asked the 22 question, but you did not review the Moretti study in 23 terms of drafting your expert report in this case; 24 correct? 25 A. Correct.</p>

22 (Pages 85 to 88)

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<p style="text-align: right;">Page 89</p> <p>1 Q. Didn't you want to have all of the author 2 testimony when making determinations about the 3 accuracy of the McGovern study? 4 MR. GORDON: Object to the form of the 5 question. 6 A. Yeah. I'm not -- all -- all of their 7 testimony or all of their work -- 8 I mean the paper, I think, pretty much 9 stands on -- on -- on its own. It justifies what 10 it -- what it did and why it did it. 11 Q. Well you reviewed the Albrecht testimony as 12 it related to the McGovern study; correct? 13 A. I did -- I did review it, yes. 14 Q. And you relied on that testimony with 15 respect to using Albrecht Exhibit 10 -- 16 A. Yes. 17 Q. -- to reanalyze the data; correct? 18 A. Yes. Well that's -- that's correct. 19 Q. And you also reviewed Mr. McGovern's 20 testimony; did you? 21 A. Yes. 22 Q. Did you review both days of testimony? 23 A. I believe I did, yes. 24 Q. And you reviewed Mr. Reed's testimony as 25 well.</p>	<p style="text-align: right;">Page 91</p> <p>1 common to use, I mean, basically use chi-square. 2 Q. One of your issues with the study is it used 3 chi-squared instead of Fisher's exact; correct? 4 A. In this particular -- 5 Yes. 6 Q. And you're not aware of perhaps why 7 Professor Nachtsheim decided to use chi-squared 8 instead of Fisher's exact. 9 A. Instead of Fish -- 10 No, I'm not -- I don't -- I don't see why I 11 would not -- if he -- 12 Whatever reasoning he might have had, I 13 would -- I would dispute that for reasons that are in 14 my report. 15 Q. And you've already said that Professor 16 Nachtsheim is an expert in statistics because he is a 17 member of The American Statistical Association; 18 correct? 19 A. He -- he is an expert. He -- he obviously 20 has interest in -- in statistics, -- 21 Q. Okay. 22 A. -- but -- 23 Q. Did you ask for Professor Nachtsheim's 24 deposition? 25 A. No, I didn't.</p>
<p style="text-align: right;">Page 90</p> <p>1 A. Yes. 2 Q. Why did you not review Professor 3 Nachtsheim's testimony? 4 A. I don't know that I -- 5 I just don't -- don't -- don't recall that. 6 I -- yeah. 7 Q. He's the only professor of statistics that 8 was an author of that study; correct? 9 A. Apparently, yes. 10 Q. Don't you think it would have been helpful 11 to review that deposition considering that you 12 reviewed the other authors' deposition testimony? 13 MR. GORDON: Object to the form of the 14 question. 15 A. It -- it -- it could have been helpful, but 16 I -- I think what -- 17 The statistical methods that were used were 18 pretty well described in the paper. 19 Q. But you're not aware of the justifications 20 for why particular methods were used according to 21 Professor Nachtsheim; correct? 22 A. I'm not sure what justifications he used, 23 but they are commonly-used statistical methods that 24 were in that paper, and so I'm -- I would not be -- 25 You know, it -- it's -- it -- it's fairly</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. Were the other deposition transcripts from 2 Mr. Albrecht, Mr. McGovern and Mr. Reed provided to 3 you? 4 A. Yes. 5 Q. And Professor Nachtsheim's deposition was 6 not provided to you. 7 A. I don't recall that it was. I -- it may 8 have been, I -- I just -- I'm -- I just don't recall 9 it. 10 Q. I'm going to put down the guard. I mean 11 don't -- don't you find that unusual, that three of 12 the authors' deposition transcripts were provided to 13 you but the only statistician's deposition transcript 14 was not? 15 MR. GORDON: Object to the form of the 16 question. 17 A. These -- yeah, I mean I -- I was -- 18 The statistical aspects of this study are 19 not terribly complicated, frankly. 20 Q. You take issue, though, with respect to the 21 tabulation of the data; correct? 22 A. Oh, it's -- you -- 23 It's important that you put the right 24 numbers down, yeah. 25 Q. And Professor Nachtsheim could have opined</p>

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<p style="text-align: right;">Page 93</p> <p>1 on the tabulation of the data; correct?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. I -- I suppose he might have. I mean the</p> <p>5 other -- the other authors certainly did.</p> <p>6 Q. And that's why you reviewed their deposition</p> <p>7 testimony; correct?</p> <p>8 A. That's -- that's part of what I -- what I --</p> <p>9 what came out of my review of their testimony, yes.</p> <p>10 Q. Is --</p> <p>11 So everything that's been marked on page 14</p> <p>12 of your report, in addition to the recent Augustine</p> <p>13 study, are the materials that you reviewed in drafting</p> <p>14 your report and providing testimony today.</p> <p>15 A. Well the recent Augus -- Augustine study I</p> <p>16 saw after --</p> <p>17 Q. Yes.</p> <p>18 A. -- this was submitted, so that's not on here</p> <p>19 because I -- I hadn't seen it when I wrote this.</p> <p>20 Q. But that's the totality of evidence up to</p> <p>21 this point in time.</p> <p>22 A. That's pretty much it, yes. Yes.</p> <p>23 MR. GORDON: I -- I think he also reviewed</p> <p>24 the Samet testimony about the Augustine article.</p> <p>25 THE WITNESS: Oh, I'm sorry, yes.</p>	<p style="text-align: right;">Page 95</p> <p>1 Exhibit 13. The title is "Forced-air warming and</p> <p>2 ultra-clean ventilation do not mix" by McGovern et al;</p> <p>3 correct?</p> <p>4 A. Correct.</p> <p>5 Q. I do not know whether you will need the</p> <p>6 study to answer these questions, but feel free to</p> <p>7 refer to it as you see fit.</p> <p>8 There were two components to this study;</p> <p>9 correct?</p> <p>10 A. That's correct.</p> <p>11 Q. There was a study of bubbles in an</p> <p>12 experimental setting, and then there was the</p> <p>13 observational data aspect of the study; correct?</p> <p>14 A. Yes.</p> <p>15 Q. And the first part of the study, which we've</p> <p>16 discussed a little bit, found a significant increase</p> <p>17 in the amount of bubbles over the surgical site in</p> <p>18 this experimental study when the Bair Hugger was used</p> <p>19 compared to a conductive warming device; correct?</p> <p>20 A. That's what they report, yes.</p> <p>21 Q. Okay. And the second part, which involved</p> <p>22 the observational data set, involved 1,437 patients;</p> <p>23 correct?</p> <p>24 A. I think that's right.</p> <p>25 Q. Table II, you might have to do a little</p>
<p style="text-align: right;">Page 94</p> <p>1 MR. SACCHET: Okay.</p> <p>2 THE WITNESS: There was also that.</p> <p>3 Q. Okay. So no other articles other than</p> <p>4 what's been listed on page 14.</p> <p>5 A. No.</p> <p>6 Q. And no other deposition transcripts aside</p> <p>7 from Samet and I think you said Augustine.</p> <p>8 A. I saw -- I saw just a couple of pages of --</p> <p>9 of Augustine, but --</p> <p>10 Q. Okay. Did you perform any independent</p> <p>11 investigation outside of what was provided to you?</p> <p>12 A. No.</p> <p>13 Q. So everything that you're relying on is what</p> <p>14 3M provided to you.</p> <p>15 A. That's correct.</p> <p>16 Q. Okay. With respect to the McGovern study,</p> <p>17 I'd like to review that quickly. I assume that we are</p> <p>18 on the same page, doctor, with calling this study "the</p> <p>19 McGovern study," which is the one that you discuss in</p> <p>20 your report; correct?</p> <p>21 A. Yes.</p> <p>22 (Exhibit 13 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. SACCHET:</p> <p>25 Q. We have handed you what has been marked as</p>	<p style="text-align: right;">Page 96</p> <p>1 math, --</p> <p>2 A. Yeah.</p> <p>3 Q. -- or I believe on page 1541 you'll see it</p> <p>4 in the bottom left-hand corner.</p> <p>5 A. Yeah. Okay.</p> <p>6 Yeah, 1066 and 371 are the two groups.</p> <p>7 Q. Which adds up though 1437.</p> <p>8 A. Okay. Yeah, right.</p> <p>9 Q. And the -- the study period was 2.5 years;</p> <p>10 correct?</p> <p>11 A. I think that's right, yes.</p> <p>12 Q. You can look at page 1540 --</p> <p>13 A. Yeah.</p> <p>14 Q. -- on the left-hand side under "Joint</p> <p>15 Infection data."</p> <p>16 A. Right.</p> <p>17 Q. And deep joint infections as opposed to</p> <p>18 superficial or wound infections was the outcome of</p> <p>19 interest; correct?</p> <p>20 A. That's correct.</p> <p>21 Q. And there were three warming phases, there</p> <p>22 was the Bair Hugger period, a transitional period, and</p> <p>23 a conductive warming period; correct?</p> <p>24 A. That's correct.</p> <p>25 Q. And during the Bair Hugger period there was</p>

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<p>1 a change in the antibiotic; correct?</p> <p>2 A. That's correct.</p> <p>3 Q. The first antibiotic was Gentamicin;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And the second antibiotic was Gentamicin</p> <p>7 plus Teicoplanin.</p> <p>8 A. That's correct.</p> <p>9 Q. Are you comfortable referring to that</p> <p>10 protocol as GenTeic?</p> <p>11 A. Okay.</p> <p>12 Q. There was also a change in the</p> <p>13 thromboprophylaxis.</p> <p>14 A. That's right.</p> <p>15 Q. The first thromboprophylaxis was tinzaparin</p> <p>16 during the Bair Hugger arm of the study; correct?</p> <p>17 A. Yes.</p> <p>18 Q. And in the last six months of the Bair</p> <p>19 Hugger arm there was a change to rivaroxaban; correct?</p> <p>20 A. That's correct.</p> <p>21 Q. Are you okay with referring to rivaroxaban</p> <p>22 as Xarelto?</p> <p>23 A. Okay.</p> <p>24 Q. It's just the pharmaceutical name of -- of</p> <p>25 that thrombo.</p>	<p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 A. I don't under -- what do you mean by --</p> <p>4 What is "marked?"</p> <p>5 Q. Have you asked Dr. Borak?</p> <p>6 A. The meaning of --</p> <p>7 It's -- it's not a quantitative term that</p> <p>8 I'm familiar with.</p> <p>9 Q. So to the extent that Dr. Borak used that</p> <p>10 language in his report, you wouldn't feel comfortable</p> <p>11 with the same language.</p> <p>12 A. I'm not fam --</p> <p>13 I have not read his report. I mean it's</p> <p>14 a -- it's a -- it's a -- it's a substantial -- it's a</p> <p>15 big decline, yes.</p> <p>16 Q. A big decline.</p> <p>17 A. It is a big difference.</p> <p>18 Q. And the p-value reported in Table II is</p> <p>19 .024; correct?</p> <p>20 A. That's -- that is the reported value, yes.</p> <p>21 Q. And that reported p-value is statistically</p> <p>22 significant based on the 95 percent confidential</p> <p>23 interval; correct?</p> <p>24 A. I would disagree with your language.</p> <p>25 Q. Okay. It's maybe not meaningful. I</p>
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<p>1 And in the Hot Dog period patients went back</p> <p>2 and received tinzaparin as opposed to Xarelto;</p> <p>3 correct?</p> <p>4 A. That's correct.</p> <p>5 Q. Okay. So results reported in Table II of</p> <p>6 this study show that three out of 371 patients</p> <p>7 developed a deep joint infection in 60 days; correct?</p> <p>8 A. That's correct.</p> <p>9 Q. And the percentage of that infection rate is</p> <p>10 .8 percent; correct?</p> <p>11 A. Correct.</p> <p>12 Q. As also reported in Table II, 32 out of</p> <p>13 1,066 patients developed a deep joint infection after</p> <p>14 receiving the Bair Hugger warming; correct?</p> <p>15 A. That's correct.</p> <p>16 Q. The change from the infection rate of the</p> <p>17 Bair Hugger --</p> <p>18 Which is three percent; correct?</p> <p>19 A. Yes.</p> <p>20 Q. -- to the .8 percent is a marked decline; is</p> <p>21 it not?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question.</p> <p>24 A. It -- it is -- it is lower, yes.</p> <p>25 Q. Would you agree that it's a marked decline?</p>	<p>1 apologize.</p> <p>2 A. Yeah. It -- it -- it is significant at the</p> <p>3 five percent level, yes.</p> <p>4 Q. Okay. So I always say this wrong, but</p> <p>5 perhaps you can edify me. If you have a statistically</p> <p>6 significant p-value using a 95 percent or five -- five</p> <p>7 percent threshold, --</p> <p>8 A. Yes.</p> <p>9 Q. -- does that mean that if you repeated the</p> <p>10 study a hundred times using the same -- a similar</p> <p>11 population of patients, that you would expect the same</p> <p>12 outcome at least 95 -- 95 times out of a hundred?</p> <p>13 A. No.</p> <p>14 Q. Okay. What --</p> <p>15 So please edify.</p> <p>16 A. What that means is if -- if there is no</p> <p>17 association and you repeat the study, you're comparing</p> <p>18 two groups where there is no effect, then just five</p> <p>19 percent of the time you will reject the -- you will</p> <p>20 reject the -- the null hypothesis, which is that there</p> <p>21 is no effect.</p> <p>22 Q. Okay. So is another way to think about it</p> <p>23 is there's a five-percent chance of getting a false</p> <p>24 positive?</p> <p>25 A. No, it's not looking at the false positive.</p>

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<p>1 Q. Okay.</p> <p>2 A. It's looking at what's the -- what's the</p> <p>3 chance that you would see this big of a difference if</p> <p>4 there was no effect.</p> <p>5 Q. Okay. Got it.</p> <p>6 A. And it's only five per --</p> <p>7 It's less than five percent, --</p> <p>8 Q. Got it.</p> <p>9 A. -- so that's a fairly rare event. So we're</p> <p>10 doing this under the null hypothesis, --</p> <p>11 Q. Yup.</p> <p>12 A. -- so therefore we would reject that</p> <p>13 hypothesis --</p> <p>14 Q. Yeah.</p> <p>15 A. -- and take the alternative.</p> <p>16 Q. Got it.</p> <p>17 A. Yeah.</p> <p>18 Q. And the odds ratio reported in Table II is</p> <p>19 3.8; correct?</p> <p>20 A. Yes, I think that's correct.</p> <p>21 Q. And would you agree with Dr. Borak's</p> <p>22 statement that that's a significantly increased odds</p> <p>23 ratio?</p> <p>24 A. Well there are two -- two parts to that.</p> <p>25 It -- it is statis -- using the approach reported, it</p>	<p>1 yes.</p> <p>2 Q. So instead of using three Hot Dog infections</p> <p>3 as reported in the study, your tabulation uses four</p> <p>4 Hot Dog infections; correct?</p> <p>5 A. We found the four based on the data in --</p> <p>6 well, it's Exhibit -- it's Exhibit 10 of --</p> <p>7 Q. Mr. Albrecht.</p> <p>8 A. -- Albrecht's and also, I mean, there's</p> <p>9 related data on that that McGovern provided and -- and</p> <p>10 whatnot.</p> <p>11 Q. Okay.</p> <p>12 A. So going back to the -- the raw data,</p> <p>13 that -- that -- that is the basis of what I report on</p> <p>14 page two.</p> <p>15 Q. And you also in that calculation used 31</p> <p>16 Bair Hugger infections as opposed to the 32 that was</p> <p>17 reported in the study; correct?</p> <p>18 A. That's -- that's correct, yeah.</p> <p>19 Q. And that's --</p> <p>20 A. It seems like in that data set there's one</p> <p>21 observation that occurred during the Hot Dog period</p> <p>22 that was attributed in the McGovern tabulation to</p> <p>23 being a -- a Bair Hugger infection when it actually</p> <p>24 occurred during the Hot Dog period, so it -- based on</p> <p>25 their description of what the -- what the study was,</p>
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<p>1 is statistically significant. The other part of it is</p> <p>2 what is the magnitude of that effect, and for the</p> <p>3 magnitude, of course, the point estimate is 3.8, which</p> <p>4 is a fairly large effect. The -- the confidence</p> <p>5 interval on the other hand, as they reported here, is</p> <p>6 1.2 to 12.5, so it's a very broad -- it's over the</p> <p>7 line of statistical significance, but the precision</p> <p>8 is --</p> <p>9 Well I mean this is a tenfold range for your</p> <p>10 95 percent confidence interval for the -- for -- for</p> <p>11 your estimate of what that effect is.</p> <p>12 Q. And I'll get to the confidence interval</p> <p>13 later on this afternoon, but with respect to just the</p> <p>14 odds ratio --</p> <p>15 A. Oh, sure.</p> <p>16 Q. -- of 3.8, do you agree with Dr. Borak that</p> <p>17 it significantly increased OR.</p> <p>18 A. Yes.</p> <p>19 Q. Significantly increased.</p> <p>20 A. It's increased, yeah.</p> <p>21 Q. Okay. On page two of your report you</p> <p>22 provide a calculation that uses different infection</p> <p>23 data than what was reported in the McGovern study;</p> <p>24 correct?</p> <p>25 A. It's different from what's in the paper,</p>	<p>1 it should have been calculated -- attributed to -- to</p> <p>2 that treatment.</p> <p>3 Q. So you said it seems that. You're not sure</p> <p>4 though; right?</p> <p>5 A. Well it's --</p> <p>6 Taking those dates, doing what they said the</p> <p>7 study was, that's what you get.</p> <p>8 Q. Okay.</p> <p>9 A. That's -- that's what I report in here.</p> <p>10 Q. But you would agree that the data in your</p> <p>11 report in terms of how many infections were in each</p> <p>12 arm of the study is different than what --</p> <p>13 A. That's correct.</p> <p>14 Q. -- the author published; correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And you just mentioned that with respect to</p> <p>17 conducting that calculation of the incidence of</p> <p>18 infection in those Bair Hugger patients and Hot Dog</p> <p>19 patients, you relied on Albrecht Exhibit 10; correct?</p> <p>20 A. Yes.</p> <p>21 MR. GORDON: Object to the form of the</p> <p>22 question. Misstates his testimony.</p> <p>23 (Exhibit 14 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. SACCHET:</p>

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<p>1 Q. I understand that there's a lot of pages in</p> <p>2 front of you, but does this appear to be the document</p> <p>3 that you reviewed in determining that there were,</p> <p>4 according to you, one more infection in the Hot Dog</p> <p>5 group and one less in the Bair Hugger group?</p> <p>6 A. It -- it -- it appears to be, yes.</p> <p>7 Q. And this document was provided to you by 3M?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. As kind of just a general statistical</p> <p>10 or epidemiological matter, you need to rely on</p> <p>11 complete data sets; correct?</p> <p>12 A. Yes.</p> <p>13 Q. And if you don't rely on complete data sets,</p> <p>14 there could be an artifact issue; correct?</p> <p>15 A. Well -- well there could be -- there could</p> <p>16 be an error in the calculation that is worth checking.</p> <p>17 Q. And that would be an artifact; right?</p> <p>18 A. Okay. Yeah.</p> <p>19 Q. Could you please turn to the Bates number</p> <p>20 AUGUSTINE -- which they all share in common -- 5277</p> <p>21 in the document.</p> <p>22 MR. GORDON: And the system.</p> <p>23 MR. SACCHET: Oh, so I can back up.</p> <p>24 Q. Are you familiar with Bates numbers, doctor?</p> <p>25 A. The base numbers? No, I'm not sure which</p>	<p>1 A. Correct.</p> <p>2 Q. Okay. And then the second page is another</p> <p>3 large table of -- mostly ends in no quantitative data;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And then the third page is a similar table,</p> <p>7 but it has kind of these -- a bunch of Ns with null</p> <p>8 values.</p> <p>9 A. Correct.</p> <p>10 Q. Okay. The fourth page is also a large table</p> <p>11 with virtually no data on it.</p> <p>12 A. Correct.</p> <p>13 Q. And the fourth page is a much narrower table</p> <p>14 that, in this instance, documents what appears to be a</p> <p>15 deep joint infection; correct?</p> <p>16 MR. GORDON: You mean the fifth page?</p> <p>17 MR. SACCHET: The fifth page. Thank you,</p> <p>18 Mr. Gordon.</p> <p>19 A. Correct.</p> <p>20 Q. And that page in particular is AUGUSTINE_</p> <p>21 0005282; correct?</p> <p>22 A. AUGUSTINE --</p> <p>23 Q. At the bottom.</p> <p>24 A. Oh, I'm sorry. Yes.</p> <p>25 Q. Okay. Let's turn to the next page and see</p>
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<p>1 ones you're talking about.</p> <p>2 Q. The Bates number is the number on the bottom</p> <p>3 of the page.</p> <p>4 MR. GORDON: Did you say 5277?</p> <p>5 MR. SACCHET: Yes.</p> <p>6 MR. GORDON: My copy doesn't have one.</p> <p>7 MR. SACCHET: Does yours?</p> <p>8 THE WITNESS: No.</p> <p>9 MR. SACCHET: Mine doesn't either.</p> <p>10 Q. Do you know whether the copy that you had</p> <p>11 had that page?</p> <p>12 A. I assumed it was all there, yeah. I</p> <p>13 didn't --</p> <p>14 Q. Well --</p> <p>15 A. Yeah, I don't -- don't recall.</p> <p>16 Q. Yeah. You didn't look at whether there was</p> <p>17 a gap in the Bates numbers that were included on the</p> <p>18 pages; did you?</p> <p>19 A. No, I didn't.</p> <p>20 Q. Okay. I'm going to try to walk you through</p> <p>21 the sequence in -- of pages here. On 5278 do you see</p> <p>22 the table?</p> <p>23 A. Yes.</p> <p>24 Q. And that table has a list of dates in column</p> <p>25 G?</p>	<p>1 if the pattern repeats itself of those five pages. Is</p> <p>2 the first page a table with a bunch of dates and other</p> <p>3 values?</p> <p>4 A. Yes.</p> <p>5 Q. Is the second table one with a bunch of Ns?</p> <p>6 A. Yes.</p> <p>7 Q. Is the third page, with the AUGUSTINE Bates</p> <p>8 number 005285, a table with null values?</p> <p>9 A. Yeah, mostly null -- N and null. Yeah.</p> <p>10 Q. Yeah. Is the fourth page, which has the</p> <p>11 Bates number AUGUSTINE_0005286, largely a blank table?</p> <p>12 A. Yes.</p> <p>13 Q. And is the fifth page, marked as AUGUSTINE_</p> <p>14 005287, a narrower table that has NOs and in one</p> <p>15 instance a YES?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. I'll represent to you that this</p> <p>18 pattern runs true through the document itself.</p> <p>19 A. Yes.</p> <p>20 Q. But if we could turn back to Bates number</p> <p>21 AUGUSTINE_005278, --</p> <p>22 A. 5278. Okay.</p> <p>23 Q. -- and the missing page that we don't have</p> <p>24 is AUGUSTINE_005277; correct?</p> <p>25 A. Correct.</p>

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<p style="text-align: right;">Page 109</p> <p>1 Q. Okay. So let's flip to AUGUSTINE_005274,</p> <p>2 which is three pages before the document.</p> <p>3 A. Okay.</p> <p>4 Q. And, excuse me, let's actually go to 5273,</p> <p>5 the page before that. That's the table like the other</p> <p>6 pages we've seen that has the dates; correct?</p> <p>7 A. Correct.</p> <p>8 Q. On 5273; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And then on 5274 we've got the big table</p> <p>11 with a bunch of Ns; correct?</p> <p>12 A. Correct.</p> <p>13 Q. And the third page, which is 5275, there are</p> <p>14 kind of the null values and other Ns; right?</p> <p>15 A. Yes.</p> <p>16 Q. Following the same pattern as the other</p> <p>17 pages we've established; correct?</p> <p>18 A. Correct.</p> <p>19 Q. And the fourth page is, like the other</p> <p>20 fourth pages in other sequences, a big table with</p> <p>21 bunches of zeroes; right?</p> <p>22 A. Bunch of blanks.</p> <p>23 Q. Yeah.</p> <p>24 A. Yeah, uh-huh.</p> <p>25 Q. And that's like the fourth page in the other</p>	<p style="text-align: right;">Page 111</p> <p>1 question, assumes facts not in evidence.</p> <p>2 A. I didn't see that there was a -- a -- a -- a</p> <p>3 miss -- a missing page in the -- in the -- the data</p> <p>4 set that I used to analyze.</p> <p>5 Q. Let's go to AUGUSTINE_5273, which was the</p> <p>6 first page of the sequence.</p> <p>7 A. Right.</p> <p>8 Q. The dates that are delineated there are from</p> <p>9 September 2008 to September 26, 2008; correct?</p> <p>10 A. September 8, yeah, twenty --</p> <p>11 Yeah, uh-huh.</p> <p>12 Q. And the Bair Hugger period of this study of</p> <p>13 the McGovern et al paper began in July of 2008;</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. And it ran until February of 2010; correct?</p> <p>17 A. Yes.</p> <p>18 Q. So this table describes operations that</p> <p>19 occurred when using the Bair Hugger in the McGovern</p> <p>20 study; correct?</p> <p>21 A. Correct.</p> <p>22 Q. So if there were an infection that would</p> <p>23 have occurred in this time period, it would have been</p> <p>24 during the Bair Hugger warming period; correct?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 110</p> <p>1 sequences we went over; correct?</p> <p>2 A. Correct.</p> <p>3 Q. The page that's missing, 5278, is the narrow</p> <p>4 table; correct?</p> <p>5 MR. GORDON: 5277 you mean?</p> <p>6 MR. SACCHET: 5277. I apologize.</p> <p>7 A. That's right.</p> <p>8 Q. And based on the sequence in the other</p> <p>9 documents we looked at, that is the table that has</p> <p>10 information as to whether or not there was a deep</p> <p>11 joint infection; correct?</p> <p>12 A. Correct.</p> <p>13 Q. So this document that you relied on in your</p> <p>14 report was missing the page that had information as to</p> <p>15 whether or not there was a deep joint infection in the</p> <p>16 time period that describes these five pages in the</p> <p>17 table.</p> <p>18 A. I --</p> <p>19 As I -- as I said, I don't -- I don't recall</p> <p>20 going over all of the -- the details in these pages</p> <p>21 and seeing that that was missing.</p> <p>22 Q. So you weren't aware that there was the</p> <p>23 missing page that included infection data regarding</p> <p>24 the use of the Bair Hugger device; correct?</p> <p>25 MR. GORDON: Object to the form of the</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. And we're missing the page in this document</p> <p>2 to know whether or not there were additional</p> <p>3 infections in the Bair Hugger period; correct?</p> <p>4 A. That --</p> <p>5 Well, that's not in this document, yes. But</p> <p>6 in the file I --</p> <p>7 I mean the numbers on my page two</p> <p>8 essentially correspond to the numbers that are in</p> <p>9 McGovern's paper, so the results I'm getting from my</p> <p>10 tabulation, with the one difference of switching the</p> <p>11 single value -- and if you go to the -- I think it's</p> <p>12 the -- one of the exhibits from the McGovern</p> <p>13 testimony, you can -- you can see where that one</p> <p>14 observation was -- was described as FAW when it should</p> <p>15 have been -- what is -- CFW or -- yeah.</p> <p>16 Q. And we'll get to the McGovern exhibit in a</p> <p>17 couple minutes, --</p> <p>18 A. Yeah.</p> <p>19 Q. -- but --</p> <p>20 A. So we do not -- there's --</p> <p>21 The numbers that we're ending up with</p> <p>22 correspond to what is in the McGovern paper.</p> <p>23 Q. So are you saying you don't feel comfortable</p> <p>24 relying on Albrecht Exhibit 10?</p> <p>25 A. Well --</p>

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<p style="text-align: right;">Page 113</p> <p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 A. The -- the data that we're looking at are</p> <p>4 derived from -- are basically from -- from --</p> <p>5 from -- from -- from this, and I'm -- it's based on a</p> <p>6 table from this that I am doing in my analysis.</p> <p>7 Q. And we're missing a page that deals with the</p> <p>8 presence or not of deep joint infection; correct?</p> <p>9 A. The -- the data file that I -- that I'm</p> <p>10 using is these same data that -- that are -- that I</p> <p>11 think are tabulated in this. They're tabulated here.</p> <p>12 Apparently, one of the pages got missed in -- when</p> <p>13 they produced -- produced this. I wasn't -- and I --</p> <p>14 you know, I wasn't shuffling through by hand</p> <p>15 everything here to -- to do the -- to do the</p> <p>16 tabulation.</p> <p>17 Q. So are you relying on McGovern 16 instead of</p> <p>18 this?</p> <p>19 A. No. Because McGovern 16, it includes</p> <p>20 additional detail that -- that corroborate the</p> <p>21 tabulations that were derived from this -- from this</p> <p>22 data set.</p> <p>23 Q. You're aware that this data set was not</p> <p>24 produced by any authors in the study; correct?</p> <p>25 MR. GORDON: Object to the form of the</p>	<p style="text-align: right;">Page 115</p> <p>1 A. I don't -- don't re --</p> <p>2 I -- I'm not -- I'm not sure I understand</p> <p>3 what you're -- what you're asking.</p> <p>4 Q. Well you just told me that this is produced</p> <p>5 by Augustine and you're relying on Exhibit 10.</p> <p>6 A. I mean Augustine's name is on it.</p> <p>7 Q. Okay.</p> <p>8 A. I don't know that he sat there in front of</p> <p>9 the computer and produced it.</p> <p>10 Q. So when you say it was produced by Dr. Scott</p> <p>11 Augustine in response to a subpoena, you don't know</p> <p>12 whether that's right or wrong.</p> <p>13 A. I -- I'm basing this on -- on what I</p> <p>14 understand -- what the -- what -- what I was given to</p> <p>15 understand of where the data came from that I was</p> <p>16 using in my analysis.</p> <p>17 Q. Who gave you that understanding?</p> <p>18 A. When I was talking to the people that --</p> <p>19 with 3M.</p> <p>20 Q. So you relied on 3M's statement that this</p> <p>21 was produced by Dr. Augustine and you accepted that</p> <p>22 statement.</p> <p>23 A. Yes, correct.</p> <p>24 Q. Did you perform any independent research to</p> <p>25 determine whether that was true or false?</p>
<p style="text-align: right;">Page 114</p> <p>1 question, lack of foundation, assumes facts not in</p> <p>2 evidence.</p> <p>3 A. I -- I don't -- I don't know who</p> <p>4 ultimately -- you know, originally produced this.</p> <p>5 Q. Why does your report on page two say that it</p> <p>6 was produced by Dr. Scott Augustine in response to a</p> <p>7 subpoena? Did you write that?</p> <p>8 A. I -- I did write that. I --</p> <p>9 That was my understanding of where the --</p> <p>10 where the file came from.</p> <p>11 Q. Dr. Augustine is not an author of the</p> <p>12 McGovern study; is he?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question, lack of foundation, assumes facts not in</p> <p>15 evidence.</p> <p>16 A. He's not listed as an author.</p> <p>17 Q. His --</p> <p>18 A. My understanding is that he had some</p> <p>19 involvement with -- with this. And I mean his name's</p> <p>20 at the bottom of this -- of this document that you</p> <p>21 just gave me.</p> <p>22 Q. So do you feel comfortable relying on</p> <p>23 documents produced by Dr. Augustine?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>	<p style="text-align: right;">Page 116</p> <p>1 A. No, I didn't.</p> <p>2 Q. Do you know whether or not Augustine was</p> <p>3 responsible for collecting the data that was</p> <p>4 eventually used in the McGovern study?</p> <p>5 A. I don't know that he did. I -- I'm sure he</p> <p>6 delegated that to someone, it must be in all</p> <p>7 likelihood, but I really don't know how this was --</p> <p>8 was -- who all as involved with producing it.</p> <p>9 Q. You don't know that Dr. Reed, an orthopedic</p> <p>10 consultant in the U.K., was the individual responsible</p> <p>11 for collecting the data?</p> <p>12 A. I know that Dr. Reed was involved with it.</p> <p>13 The -- the management organization of that is -- is --</p> <p>14 is something I don't know.</p> <p>15 Q. Would knowing that Dr. Reed was in charge of</p> <p>16 collecting the data instead of Dr. Augustine give you</p> <p>17 any pause as to whether this is the final data set?</p> <p>18 MR. GORDON: Object to the form of the</p> <p>19 question.</p> <p>20 A. I have --</p> <p>21 I mean if -- if Dr. Reed produced it and --</p> <p>22 and Dr. Augustine supplied it, I -- I'm taking the</p> <p>23 values as they are. I mean I -- I was just analyzing</p> <p>24 the data that I was -- that I was shown.</p> <p>25 Q. Has anyone ever asked you for data based on</p>

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<p>1 a published cit -- an article that you published?</p> <p>2 A. Yes.</p> <p>3 Q. And did you provide the data?</p> <p>4 A. Very often it's -- I'm --</p> <p>5 I'm often collaborating with another</p> <p>6 investigator, so -- so the -- I would usually go to --</p> <p>7 go to the co-author who owned the data set and they</p> <p>8 would be involved with the decision on whether or not</p> <p>9 to provide it.</p> <p>10 Q. You'd go to a co-author.</p> <p>11 A. Yes. Well it's often the main author of</p> <p>12 the -- of the paper.</p> <p>13 Q. Reed was an author of the --</p> <p>14 A. Yes.</p> <p>15 Q. -- of the article; right?</p> <p>16 A. That's right, he was the senior author.</p> <p>17 Q. Did you do any investigation to determine</p> <p>18 whether Mr. Reed produced a data set?</p> <p>19 A. No, I didn't.</p> <p>20 Q. So you don't know whether or not Mr. Reed</p> <p>21 produced the data set as an author of the study that</p> <p>22 corroborates the data noted in the McGovern study.</p> <p>23 A. I don't -- don't know that the -- that</p> <p>24 the -- that -- that that's what -- what transpired.</p> <p>25 Q. You didn't attempt to determine that though.</p>	<p>1 the funding came from Augustine; correct?</p> <p>2 A. Well as I say, I --</p> <p>3 Oh, I don't know.</p> <p>4 Q. I'll represent to you that there's no</p> <p>5 mention of Augustine in the McGovern study. You're</p> <p>6 not going to find it.</p> <p>7 A. There -- there is -- there is not. I -- I</p> <p>8 have acknowledged that there's no -- there's no</p> <p>9 specific reference to -- to Augustine. However, I</p> <p>10 believe he did have some -- some involvement with</p> <p>11 the -- the production of this work.</p> <p>12 Q. Have you reviewed the Augustine deposition?</p> <p>13 A. I've seen some of it. Not the whole thing.</p> <p>14 Q. Did Augustine's deposition testimony</p> <p>15 corroborate the fact that he was involved in this</p> <p>16 study, the McGovern study?</p> <p>17 A. As I say, I don't -- I haven't seen the</p> <p>18 whole -- whole of the deposition.</p> <p>19 Q. So you have no basis to conclude that</p> <p>20 actually Augustine was involved in the McGovern study.</p> <p>21 A. Well as I -- as I say, I -- there was --</p> <p>22 There is this issue of where some of the</p> <p>23 funding was coming from for doing the McGovern study,</p> <p>24 and I'm not putting my fingers on it right -- right at</p> <p>25 the moment, so it was part of what I'm -- what I'm</p>
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<p>1 A. No, I didn't.</p> <p>2 Q. And you agree with me that Augustine is not</p> <p>3 a noted author on the study; correct?</p> <p>4 A. He is not. He is not listed as an author,</p> <p>5 yes.</p> <p>6 Q. So you relied on a third party's production</p> <p>7 of a data set with respect to the McGovern study.</p> <p>8 A. Well while he's not an author, I don't know</p> <p>9 if he was involved in fact.</p> <p>10 Q. So you don't know whether he was involved,</p> <p>11 but you still relied on his data set.</p> <p>12 A. Well he had some involvement with -- with</p> <p>13 this -- with this group. I think --</p> <p>14 Q. Does it say that on the study?</p> <p>15 A. I mean where --</p> <p>16 I forget where the funding comes from.</p> <p>17 Q. The last page of the study will tell you if</p> <p>18 there were any benefits. The very last page, very</p> <p>19 last page. Anything say Augustine?</p> <p>20 A. I don't think --</p> <p>21 I don't see anything that says Augustine,</p> <p>22 I -- but that was not the point that I was -- was</p> <p>23 making. I'm not sure where the funding for this work</p> <p>24 came from.</p> <p>25 Q. So you have no basis to know whether or not</p>	<p>1 saying.</p> <p>2 Q. Where did you get the idea?</p> <p>3 A. One of the -- one of the articles -- one of</p> <p>4 the things that I've read -- that I read in preparing</p> <p>5 this report.</p> <p>6 Q. One of the things in the 19 sources listed</p> <p>7 on Ex -- on page 14 of your report?</p> <p>8 A. I believe it was somewhere in there, yes,</p> <p>9 but --</p> <p>10 I mean Albrecht, as I understand it, is --</p> <p>11 was -- is an Augustine -- is working for Augustine.</p> <p>12 Q. Does it say that on the paper?</p> <p>13 A. It doesn't say that on the paper, but --</p> <p>14 Q. You're assuming that to be true.</p> <p>15 A. I think it says that in --</p> <p>16 I think Albrecht says -- said that in his --</p> <p>17 his deposition.</p> <p>18 Q. Are you sure?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. I would have to review his testimony again,</p> <p>22 but it -- it -- it has appeared many -- in -- in</p> <p>23 many -- many things that they -- they are -- they</p> <p>24 are -- they are together, and --</p> <p>25 Q. 3M told you this.</p>

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<p style="text-align: right;">Page 121</p> <p>1 A. Well I --</p> <p>2 Q. You said that earlier, five minutes ago.</p> <p>3 A. I --</p> <p>4 They -- they -- they've -- they've said</p> <p>5 that. I said -- as I say, I've also -- I've read it</p> <p>6 in either a defi -- a deposition or one of the other</p> <p>7 things that was -- that -- that I -- that I read, and</p> <p>8 maybe in one of the other papers or something like</p> <p>9 that.</p> <p>10 Q. So you said you read Mr. Albrecht's</p> <p>11 deposition; correct?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And are you familiar with the fact</p> <p>14 that in Mr. Albrecht's deposition he said that the</p> <p>15 data set that was analyzed in terms of conducting this</p> <p>16 study contains three infections in the Hot Dog period?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, misstates the testimony.</p> <p>19 A. I -- I don't recall exactly what he said.</p> <p>20 Q. So you have no recollection as to whether</p> <p>21 Mr. Albrecht actually did say that the data set</p> <p>22 contained three infections for the Hot Dog period.</p> <p>23 A. I don't remember that.</p> <p>24 Q. Well you rely on Mr. Albrecht's testimony in</p> <p>25 determining that Albrecht Exhibit 10 in fact is the</p>	<p style="text-align: right;">Page 123</p> <p>1 was the final data set; does he?</p> <p>2 A. I don't know.</p> <p>3 MR. GORDON: Object to the form of the</p> <p>4 question, lacks foundation.</p> <p>5 Q. He called it the apparent data set; doesn't</p> <p>6 he?</p> <p>7 MR. GORDON: Same objection.</p> <p>8 A. As I say, I have not -- I have not seen his</p> <p>9 report.</p> <p>10 Q. Okay.</p> <p>11 (Exhibit 15 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. Exhibit 15 is the October 7, 2016 deposition</p> <p>15 of Mr. Albrecht; correct, Dr. Holford?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay. If you could please turn to page 158</p> <p>18 of the transcript, which is page 41 at the bottom. Do</p> <p>19 you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Mr. Gordon asked, "If you count the</p> <p>22 infections for that time period, June 1st 2010, to</p> <p>23 December 31st, 2010, there are actually four,</p> <p>24 correct?"</p> <p>25 Do you see that question?</p>
<p style="text-align: right;">Page 122</p> <p>1 final data set; correct?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. I -- I don't know that this is the data</p> <p>5 set --</p> <p>6 I mean the numbers don't agree with what was</p> <p>7 tabulated in the -- in the -- in -- in the McGovern</p> <p>8 paper, --</p> <p>9 Q. Okay.</p> <p>10 A. -- so I mean I'm not sure where Albrecht did</p> <p>11 the tab -- how -- how Albrecht did -- did the</p> <p>12 tabulation.</p> <p>13 Q. But you rely on Mr. Albrecht's testimony</p> <p>14 to -- in relying on using Exhibit 10; correct?</p> <p>15 A. Using Exhibit 10. But then when you</p> <p>16 tabulate Exhibit 10, you don't get what's in the</p> <p>17 paper.</p> <p>18 Q. Yeah. So you don't know whether Exhibit 10</p> <p>19 is the final data set.</p> <p>20 A. It --</p> <p>21 I don't know that it is the data set that he</p> <p>22 used with this paper or --</p> <p>23 Maybe he made a mistake in the tabulation.</p> <p>24 I don't know.</p> <p>25 Q. Mr. -- or Dr. Borak doesn't conclude that it</p>	<p style="text-align: right;">Page 124</p> <p>1 A. Yes.</p> <p>2 Q. And Mr. Albrecht responds, "I would have to</p> <p>3 physically count these, but that's not what our data</p> <p>4 set says here. The data set that was analyzed there</p> <p>5 was three."</p> <p>6 A. Yes.</p> <p>7 Q. Are you aware that Mr. Albrecht testified</p> <p>8 that the data set that was analyzed had three deep</p> <p>9 joint infections instead of the four that Mr. Gordon</p> <p>10 had asked about?</p> <p>11 A. That's what -- that's what he's saying here,</p> <p>12 and that corresponds to the --</p> <p>13 Q. The study.</p> <p>14 A. -- the -- the -- the -- the Table -- the</p> <p>15 Table II in this -- in the paper.</p> <p>16 Q. But in your report you say that the results</p> <p>17 by McGovern are incorrect because they arise from an</p> <p>18 incorrect tabulation error; an error is recognized in</p> <p>19 the deposition by Albrecht.</p> <p>20 A. You're looking at one piece of it here.</p> <p>21 There's elsewhere that he -- that -- that he talks</p> <p>22 about a -- that -- that there were -- there was</p> <p>23 apparently an error that they recognized later.</p> <p>24 Q. You think Mr. Albrecht said that?</p> <p>25 A. I thought he did somewhere. I -- I don't</p>

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<p>1 remember exactly where -- where it is.</p> <p>2 Reed said it.</p> <p>3 Q. This is Mr. Albrecht. Do you think Mr.</p> <p>4 Albrecht said there was an error?</p> <p>5 A. I seem to recall he -- that -- that there</p> <p>6 was. I don't remember exactly where -- where it is.</p> <p>7 It's a fairly long report.</p> <p>8 Q. Let's keep going then. If you can go to</p> <p>9 internal page 142, page 37 at the bottom, line 16, Mr.</p> <p>10 Gordon asked, "I have something that's going to help.</p> <p>11 But first I want to establish that -- that is a</p> <p>12 printout of the data that Dr. Reed would have provided</p> <p>13 to you and from which you generated your statistical</p> <p>14 analysis that became the observational component of</p> <p>15 Exhibit 8."</p> <p>16 Do you see that question?</p> <p>17 A. Yes.</p> <p>18 Q. I'll represent to you that Exhibit 8 is the</p> <p>19 McGovern study --</p> <p>20 A. Okay.</p> <p>21 Q. -- and I'll also represent to you that the</p> <p>22 data set that Mr. Gordon is referring to is Albrecht</p> <p>23 Exhibit 10.</p> <p>24 A. Okay.</p> <p>25 Q. The answer is, "I'm assuming, but there's no</p>	<p>1 Q. Yeah.</p> <p>2 A. Yeah.</p> <p>3 Q. And Mr. Albrecht in this testimony is saying</p> <p>4 he doesn't know whether it's the final data set.</p> <p>5 A. Okay.</p> <p>6 Q. And Mr. Albrecht also said in the testimony</p> <p>7 we read a moment ago that there were three infections</p> <p>8 in the Hot Dog arm that were analyzed with respect to</p> <p>9 the paper; correct?</p> <p>10 A. That's --</p> <p>11 He's, I assume, re -- reporting back what --</p> <p>12 what was actually published in the paper, what this</p> <p>13 tabulation that's in the paper showed.</p> <p>14 Q. He says the data set that was analyzed there</p> <p>15 was three.</p> <p>16 A. So what is he referring --</p> <p>17 When he says "data set," what does he mean?</p> <p>18 I don't know quite what he -- what he's referring to.</p> <p>19 Is he referring to the data -- the tabulation that was</p> <p>20 made from the data, or is he talking about the -- the</p> <p>21 original file?</p> <p>22 Q. You're aware that not even Mr. Gordon knows</p> <p>23 whether Exhibit 10 is the final data set; correct?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question, lack of foundation.</p>
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<p>1 way for me to verify something like this."</p> <p>2 A. Okay.</p> <p>3 Q. So Mr. Albrecht didn't know whether or not</p> <p>4 Albrecht Exhibit 10 was the final data set, correct,</p> <p>5 based on this testimony?</p> <p>6 A. I -- I --</p> <p>7 Yeah. Apparently, yeah.</p> <p>8 Q. But you have concluded that, based on Mr.</p> <p>9 Albrecht's testimony, that Albrecht Exhibit 10 is the</p> <p>10 final data set; is that correct?</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question, misstates his test -- misstates prior</p> <p>13 testimony.</p> <p>14 Q. Is your testimony not that Albrecht Exhibit</p> <p>15 10 is the final data set?</p> <p>16 MR. GORDON: Same objection.</p> <p>17 A. I don't -- I don't --</p> <p>18 I'm taking Exhibit 10 as it -- as it -- as</p> <p>19 it is. I mean what --</p> <p>20 What do you mean by "final data set?"</p> <p>21 Q. Well you've already said that the data set</p> <p>22 that is in Albrecht 10 is not the data that was in the</p> <p>23 study; correct?</p> <p>24 A. A tabulation based on -- based on that --</p> <p>25 that data set doesn't agree with the paper.</p>	<p>1 A. I don't know what Mr. Gordon knows or</p> <p>2 doesn't know about that.</p> <p>3 Q. Let's look at page 163, which is 42 at the</p> <p>4 bottom. Are you there, doctor?</p> <p>5 A. Okay.</p> <p>6 Q. Line 17, Mr. Gordon asks -- or states, "And</p> <p>7 I want to make it very clear, I have no idea if</p> <p>8 Exhibit 10 is the original data" --</p> <p>9 Albrecht answers: "I don't either."</p> <p>10 Do you see that?</p> <p>11 A. Okay.</p> <p>12 Q. So Mr. Gordon doesn't know if it's the final</p> <p>13 data set, Mr. Albrecht doesn't know whether it's the</p> <p>14 final data set, Mr. Borak in his report uses the word</p> <p>15 "apparent" data set, you don't know whether it's the</p> <p>16 final data set --</p> <p>17 A. Well the question is not "final," question</p> <p>18 is "original."</p> <p>19 Q. Okay. So let's say the original data set.</p> <p>20 A. Okay.</p> <p>21 Q. Mr. Gordon doesn't know if Exhibit 10 is the</p> <p>22 original data set.</p> <p>23 A. Okay.</p> <p>24 Q. Mr. Albrecht also doesn't know whether</p> <p>25 Exhibit 10 is the original data set.</p>

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<p>1 A. Yeah.</p> <p>2 Q. Mr. Borak also doesn't know whether Exhibit</p> <p>3 10 is the original data set.</p> <p>4 A. Okay.</p> <p>5 Q. And you don't know.</p> <p>6 A. I don't.</p> <p>7 Q. To the extent that you rely on Albrecht</p> <p>8 Exhibit 10, not knowing whether or not it's the</p> <p>9 original data set, it could be a data artifact issue;</p> <p>10 could it not?</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question.</p> <p>13 A. If -- if there's an error in -- in --</p> <p>14 I mean if -- if the file is not the correct</p> <p>15 data, then there -- there could be -- there -- there</p> <p>16 would be a problem with -- with the analysis.</p> <p>17 Q. And -- and you don't know whether or not</p> <p>18 there is a problem with the data.</p> <p>19 A. I don't know. I don't know if there is or</p> <p>20 if there is not.</p> <p>21 Q. You know that there's a missing page.</p> <p>22 A. You --</p> <p>23 There is one missing page.</p> <p>24 Q. You know that the missing page contains or</p> <p>25 may not contain information regarding deep joint</p>	<p>1 Mr. Albrecht has said that the data set that was</p> <p>2 analyzed, there was three deep joint infections.</p> <p>3 A. Yes.</p> <p>4 Q. You're making that assumption even though</p> <p>5 Mr. Gordon said that Exhibit 10, he didn't know</p> <p>6 whether it was the original data set.</p> <p>7 MR. GORDON: You're -- you're actually --</p> <p>8 You're reading only a portion of the</p> <p>9 testimony and you're --</p> <p>10 MR. SACCHET: I think you're testifying</p> <p>11 right now, Mr. Gordon.</p> <p>12 MR. GORDON: Well no. I mean --</p> <p>13 But come on.</p> <p>14 MR. SACCHET: I'm --</p> <p>15 MR. GORDON: If you're going to quote me,</p> <p>16 quote what I said; don't make -- don't -- don't --</p> <p>17 MR. SACCHET: Okay.</p> <p>18 MR. GORDON: -- don't screw up the record by</p> <p>19 selectively quoting half of what I said.</p> <p>20 MR. SACCHET: Yeah. I'll read the sentence.</p> <p>21 MR. GORDON: Read the whole sentence.</p> <p>22 MR. SACCHET: "And I want -- I want to make</p> <p>23 it very clear, I have no idea if Exhibit 10 is the</p> <p>24 original data" --</p> <p>25 MR. GORDON: And you see the thing it says</p>
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<p>1 infection during the Bair Hugger study period;</p> <p>2 correct?</p> <p>3 A. It was --</p> <p>4 I wasn't looking at the individual pages, as</p> <p>5 I've -- as I've said, --</p> <p>6 Q. Yeah.</p> <p>7 A. -- and -- and my under -- I --</p> <p>8 I don't know if this is the same data set</p> <p>9 that -- that Albrecht was -- was looking at when he</p> <p>10 did the -- his -- his calculations.</p> <p>11 Q. Thank you.</p> <p>12 Do you have any other reason to assume that</p> <p>13 Albrecht Exhibit 10 is the original or final data set?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. I mean why is Exhibit 10 as part of the</p> <p>17 Albrecht testimony?</p> <p>18 Q. Why is it?</p> <p>19 A. Yeah. How did it get there?</p> <p>20 Q. Mr. Gordon marked --</p> <p>21 A. Okay.</p> <p>22 Q. -- Exhibit 10 at the deposition.</p> <p>23 A. And I mean the assumption is is that that is</p> <p>24 the data on which this is based.</p> <p>25 Q. You're making that assumption even though</p>	<p>1 after that? It says dash --</p> <p>2 MR. SACCHET: Dash.</p> <p>3 MR. GORDON: -- and continues on with the</p> <p>4 rest of what I said.</p> <p>5 MR. SACCHET: -- "or the -- the newer data</p> <p>6 that's slightly conflicted."</p> <p>7 Q. Does that change your mind?</p> <p>8 A. What is the question?</p> <p>9 Q. The question is: Mr. Albrecht has said that</p> <p>10 there was three infections in the Hot Dog period based</p> <p>11 on the data that was analyzed.</p> <p>12 A. Yes.</p> <p>13 Q. Mr. Gordon has said he doesn't know if</p> <p>14 Exhibit 10 is the original data or the newer data</p> <p>15 that's slightly conflicted.</p> <p>16 A. Yes.</p> <p>17 Q. Dr. Borak has said that it apparently could</p> <p>18 be.</p> <p>19 A. Yes.</p> <p>20 Q. You just told me that you're assuming</p> <p>21 Albrecht Exhibit 10 is the final data set.</p> <p>22 MR. GORDON: I object to the form of the</p> <p>23 question.</p> <p>24 A. Well I'm -- I'm -- that --</p> <p>25 Exhibit 10 is the data on which I did the</p>

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<p>1 analysis, --</p> <p>2 Q. Okay.</p> <p>3 A. -- so in --</p> <p>4 The total number of infections in my table</p> <p>5 exactly -- are exactly the same as what are in</p> <p>6 McGovern's paper.</p> <p>7 Q. Okay. Do you rely on anything else to</p> <p>8 conclude that Albrecht Exhibit 10 is the original</p> <p>9 data?</p> <p>10 MR. GORDON: Objection --</p> <p>11 Q. That's -- that's -- that's the scope of the</p> <p>12 question.</p> <p>13 MR. GORDON: Objection, asked and answered.</p> <p>14 Q. Do you rely on anything else?</p> <p>15 MR. GORDON: Objection, asked and answered.</p> <p>16 He's also testified the other things he relied on.</p> <p>17 MR. SACCHET: I don't recall the other</p> <p>18 testimony. I'm not -- I'm not --</p> <p>19 MR. GORDON: All right. Fair enough.</p> <p>20 A. I mean I -- I've -- I'm assuming that those</p> <p>21 are --</p> <p>22 The data that -- that formed the basis of --</p> <p>23 of that -- of the McGovern paper, that they're in --</p> <p>24 that they're in that file.</p> <p>25 Q. I'm going to ask the question again. Do you</p>	<p>1 Q. So anything else in addition to McGovern 16?</p> <p>2 MR. GORDON: Again, asked and answered.</p> <p>3 A. Yeah. Anything --</p> <p>4 It's 10, 16 and -- well, an analysis of</p> <p>5 those. I'm not recalling other sources at the moment,</p> <p>6 but --</p> <p>7 Q. Okay. Thank you. That answers the</p> <p>8 question.</p> <p>9 A. Yeah.</p> <p>10 Q. Before we get to McGovern 16, I'd like to</p> <p>11 show you a few additional documents.</p> <p>12 (Exhibit 16 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. SACCHET:</p> <p>15 Q. Have you seen this document before,</p> <p>16 Professor Holford?</p> <p>17 A. I don't recall seeing this.</p> <p>18 Q. Okay. It has been produced by Mr. Albrecht</p> <p>19 based on the Bates number in the bottom right-hand</p> <p>20 corner; correct? It --</p> <p>21 The bottom right-hand Bates number has the</p> <p>22 prefix "Albrecht."</p> <p>23 A. Oh, I'm sorry. Yes. Yes.</p> <p>24 Q. And the top of the page is entitled</p> <p>25 "LogisticRegression, Mark Albrecht, March 11, 2016."</p>
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<p>1 rely on anything else in making that assumption?</p> <p>2 A. Well I've --</p> <p>3 There are other parts of the data that have</p> <p>4 been given as some of the other -- other evidence.</p> <p>5 Q. What?</p> <p>6 A. Well there's a list of -- of the infections</p> <p>7 that I think McGovern --</p> <p>8 Q. Okay.</p> <p>9 A. -- provided, the evi -- well I think</p> <p>10 it's -- I think it was Exhibit 16 in his -- his</p> <p>11 deposition.</p> <p>12 Q. Okay.</p> <p>13 A. And, you know, it's -- it's a different</p> <p>14 file. There are differences in there, differences in</p> <p>15 the way the dates are recorded because we're dealing</p> <p>16 with the way the Brits give dates and the way we give</p> <p>17 dates in the U.S. and things like that. But you can</p> <p>18 match up the -- those two -- two files and they -- you</p> <p>19 know, they -- they agree. And so it -- that has given</p> <p>20 me more confidence that the data that we're looking --</p> <p>21 that I'm looking at really corresponds to the same</p> <p>22 data --</p> <p>23 Q. Okay.</p> <p>24 A. -- that -- that forms the basis of the --</p> <p>25 the report in McGovern.</p>	<p>1 A. Correct.</p> <p>2 Q. That's a number of years after the</p> <p>3 publication of the McGovern study; correct?</p> <p>4 A. Okay. Yeah. Yes, it is.</p> <p>5 Q. And the first paragraph says, "Below is the</p> <p>6 analysis source code and data supporting the</p> <p>7 publication Forced-air warming linked to</p> <p>8 periprosthetic total joint replacement infections.</p> <p>9 This s an R-markdown document, so it can be run</p> <p>10 directly in the R-Console to produce -- to reproduce</p> <p>11 the results." Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And then the next title is "Raw Data" and it</p> <p>14 says, "The raw infection data by hospital is, colon;"</p> <p>15 correct? That's -- that's what it says, "The raw</p> <p>16 infection data by hospital is, colon."</p> <p>17 A. Yes.</p> <p>18 Q. And there's some quotes.</p> <p>19 If you look on the fourth line of that we</p> <p>20 see "c(10, 11, 10, 21, 3, 32);" correct?</p> <p>21 A. Yes.</p> <p>22 Q. And then we see "NonInfections equal c(1087,</p> <p>23 378, 1087, 656, 368, 1034)." Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. Do the numbers 3, 32, 368 and 1034 ring a</p>

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<p style="text-align: right;">Page 137</p> <p>1 bell?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. No.</p> <p>5 Q. The numbers 3 and 32 are not the same</p> <p>6 numbers that were used in the McGovern publication</p> <p>7 with respect to the total number of infections in the</p> <p>8 Hot Dog arm versus the Bair Hugger arm?</p> <p>9 A. Which --</p> <p>10 I don't understand what you're asking.</p> <p>11 Q. Okay. In the Bair Hugger period, how many</p> <p>12 infections did the authors report with respect to the</p> <p>13 Hot Dog, the authors report in Table II?</p> <p>14 A. Table II.</p> <p>15 Q. Did they report three in Table II, Hot Dog</p> <p>16 infections?</p> <p>17 A. Yeah.</p> <p>18 Q. Okay. How many Bair Hugger infections did</p> <p>19 they report in the McGovern study?</p> <p>20 A. Thirty-two.</p> <p>21 Q. Is that the same number that we see here?</p> <p>22 A. Oh, oh, I see. This is --</p> <p>23 I'm -- I'm sorry, I don't -- I'm not really</p> <p>24 understanding this code.</p> <p>25 Okay. So what is this c?</p>	<p style="text-align: right;">Page 139</p> <p>1 Table II from the Bair Hugger period?</p> <p>2 A. That's correct.</p> <p>3 Q. Were there 368 non-infections in the Hot Dog</p> <p>4 period reported in the McGovern study?</p> <p>5 A. Yes.</p> <p>6 Q. Were there a hundred and -- 1,034 non-</p> <p>7 infections reported in the Bair Hugger -- in the</p> <p>8 McGovern study with respect to the Bair Hugger arm?</p> <p>9 A. Yes.</p> <p>10 Q. These numbers are the same as what was</p> <p>11 reported in the Bair Hugger study, the numbers are the</p> <p>12 same -- it's a simple question -- as reported in the</p> <p>13 McGovern study.</p> <p>14 A. The last -- the last two -- two columns of</p> <p>15 this vector do correspond to that. I don't know what</p> <p>16 the other numbers that are there correspond to. I</p> <p>17 don't know what the 10 --</p> <p>18 The 1087, for example, what is that?</p> <p>19 Q. I'm not asking about those numbers.</p> <p>20 A. Well I have to understand when I'm reading</p> <p>21 someone's code. I don't understand what it's</p> <p>22 referring to.</p> <p>23 Q. And the date is March 11, 2016; correct?</p> <p>24 A. Yes.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 138</p> <p>1 Q. "Center" perhaps.</p> <p>2 A. No. I think it's a vector usually in R,</p> <p>3 it's a vector and it --</p> <p>4 Q. My -- my -- my question --</p> <p>5 MR. GORDON: Counsel, I mean, you know --</p> <p>6 A. I don't know what --</p> <p>7 MR. SACCHET: Corey, again it's a speaking</p> <p>8 objection. If you want to object, go for it.</p> <p>9 MR. GORDON: Yeah. If you're representing</p> <p>10 this has anything to do with the McGovern paper --</p> <p>11 MR. SACCHET: Yeah?</p> <p>12 MR. GORDON: -- as opposed to what the</p> <p>13 testimony was, which was this was what turned into the</p> <p>14 Augustine -- recently published Augustine paper, you</p> <p>15 know, you've got -- you've got an obligation to --</p> <p>16 to -- to be truthful.</p> <p>17 MR. SACCHET: I'm look -- I --</p> <p>18 My questions are solely about the numbers.</p> <p>19 Q. Professor Holford, were there three</p> <p>20 infections in the Hot Dog period in the McGovern</p> <p>21 study --</p> <p>22 A. Looking at the paper, yes.</p> <p>23 Q. -- as reported in Table II?</p> <p>24 A. As reported in Table II, yes.</p> <p>25 Q. Were there 32 infections as reported in</p>	<p style="text-align: right;">Page 140</p> <p>1 MR. GORDON: I'm going to need a quick break</p> <p>2 in the near future, --</p> <p>3 MR. SACCHET: Okay.</p> <p>4 MR. GORDON: -- whenever it's convenient.</p> <p>5 MR. SACCHET: Okay. Take about five minutes</p> <p>6 if you don't mind.</p> <p>7 MR. GORDON: Right now?</p> <p>8 MR. SACCHET: Just in five minutes.</p> <p>9 MR. GORDON: Oh, that's fine.</p> <p>10 (Exhibit 17 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. SACCHET:</p> <p>13 Q. This is a document with a subject line "Full</p> <p>14 workup of the stats you requested;" correct?</p> <p>15 A. Yes.</p> <p>16 Q. It's been previously marked as McGovern 23;</p> <p>17 correct?</p> <p>18 A. I don't know where you're getting that from.</p> <p>19 Q. The bottom right of the page, there's a</p> <p>20 stamp there and it says Exhibit --</p> <p>21 A. Oh, I see.</p> <p>22 Q. -- Exhibit McGovern 23.</p> <p>23 A. Yeah.</p> <p>24 Q. Have you seen this document before?</p> <p>25 A. No.</p>

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<p style="text-align: right;">Page 141</p> <p>1 Q. This was a document that was --</p> <p>2 I'll represent to you this is a document</p> <p>3 that was marked at the McGovern deposition.</p> <p>4 You reviewed other exhibits from the</p> <p>5 McGovern deposition; correct?</p> <p>6 A. I looked at, I think, some of them, yeah.</p> <p>7 Q. One of them was McGovern Exhibit 16;</p> <p>8 correct?</p> <p>9 A. Oh. Yes, I did.</p> <p>10 Q. But you didn't see this one.</p> <p>11 A. No, I didn't look at this one.</p> <p>12 Q. Did you get all of the exhibits from these</p> <p>13 depositions or just a select handful?</p> <p>14 A. I think they were all there. I didn't -- I</p> <p>15 didn't do an audit to check, but --</p> <p>16 Q. How did you determine which ones to look at</p> <p>17 and which ones not to look at?</p> <p>18 A. It was what was most relevant to the</p> <p>19 analysis that I was doing.</p> <p>20 Q. How did you make that determination?</p> <p>21 A. Well I was -- figured out what I was</p> <p>22 interested in for that particular part of the report I</p> <p>23 was working on.</p> <p>24 Q. Okay. Let's see if this piques your</p> <p>25 interest. The first e-mail is dated November 29th,</p>	<p style="text-align: right;">Page 143</p> <p>1 A. Yes.</p> <p>2 Q. And the percentage .9?</p> <p>3 A. Yes.</p> <p>4 Q. And then there were 792 of whom did not</p> <p>5 develop an infection; correct?</p> <p>6 A. Yes.</p> <p>7 Q. That's approximately double the amount of</p> <p>8 patients that were originally analyzed in the Bair</p> <p>9 Hugger period; correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. So this appears to be an extended</p> <p>12 data set; correct?</p> <p>13 A. It appears that they've extended the</p> <p>14 conductive fabric, --</p> <p>15 Q. Okay.</p> <p>16 A. -- yeah.</p> <p>17 Q. Let's look at the forced-air group. How</p> <p>18 many individuals developed an infection?</p> <p>19 A. Thirty-three.</p> <p>20 Q. That's two more than the 31 that you use in</p> <p>21 your report; correct?</p> <p>22 A. Okay.</p> <p>23 Q. Is that correct?</p> <p>24 A. Appears to be correct. Yeah, I used --</p> <p>25 Q. Thirty-one; correct?</p>
<p style="text-align: right;">Page 142</p> <p>1 2011; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And that is after publication of the</p> <p>4 McGovern study; correct?</p> <p>5 A. I believe so, yes.</p> <p>6 Q. Okay. And in the e-mail on November 30th,</p> <p>7 2011 from Mike Reed to Mark Albrecht, the text states,</p> <p>8 "Mark</p> <p>9 "This is great. I am very grateful.</p> <p>10 So - for clarity - this chart is the same as</p> <p>11 the one in our paper but with longer follow up?"</p> <p>12 Do you see that?</p> <p>13 A. Okay. Yes.</p> <p>14 Q. And then the last line says, "You are 3.6</p> <p>15 times more likely to get an infection on FAW than</p> <p>16 CFW?" Correct?</p> <p>17 Last line of that same paragraph.</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Now if we turn the page, Table I does</p> <p>20 in fact look like Table II in the McGovern study;</p> <p>21 correct?</p> <p>22 A. It looks like it, yes.</p> <p>23 Q. Okay. Let's look at the number of patients</p> <p>24 developing infection in the conductive fabric warming</p> <p>25 group. Do you see the number seven?</p>	<p style="text-align: right;">Page 144</p> <p>1 A. I have 32.</p> <p>2 Well wait, I'm sorry. Yeah, 31, that's</p> <p>3 right.</p> <p>4 Q. This is two more.</p> <p>5 A. It is two more.</p> <p>6 Q. And the percent of infection is 3.1 in the</p> <p>7 forced-air group; correct?</p> <p>8 A. Yes.</p> <p>9 Q. That is in fact higher than the percent that</p> <p>10 was reported in the study; correct?</p> <p>11 A. Yes.</p> <p>12 Q. That's higher than the percent that you use</p> <p>13 in your report; correct?</p> <p>14 A. Yes.</p> <p>15 Q. Do you have any basis to conclude that this</p> <p>16 data is not the final data set?</p> <p>17 MR. GORDON: Which data?</p> <p>18 MR. SACCHET: The numbers reported here.</p> <p>19 MR. GORDON: In --</p> <p>20 A. What do you mean by "final data set?" I</p> <p>21 mean --</p> <p>22 MR. GORDON: -- Exhibit 17.</p> <p>23 A. This is very different from --</p> <p>24 It's not the data set that appears in</p> <p>25 McGovern.</p>

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<p style="text-align: right;">Page 145</p> <p>1 Q. With respect to the forced-air group, there</p> <p>2 are two more infections; correct?</p> <p>3 A. There -- there are.</p> <p>4 MR. GORDON: Two more infections than he</p> <p>5 did -- he reported.</p> <p>6 A. Two more than I -- than I reported. It is</p> <p>7 one more than McGovern reported.</p> <p>8 Q. Okay.</p> <p>9 A. And the total number is --</p> <p>10 What is it?</p> <p>11 Q. One thousand --</p> <p>12 A. 1,098.</p> <p>13 Q. You mean 68?</p> <p>14 A. Thirty-two and 1066.</p> <p>15 Oh, I'm sorry, 1068 is the total.</p> <p>16 Q. Yeah.</p> <p>17 A. So this is --</p> <p>18 This says 1065 are in this report you're</p> <p>19 just showing me.</p> <p>20 Q. Uh-huh. Does this calculation give you any</p> <p>21 pause that perhaps there was more Bair Hugger</p> <p>22 infections than the amount that you've reported in</p> <p>23 your report?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>	<p style="text-align: right;">Page 147</p> <p>1 Q. Yes.</p> <p>2 A. Okay. So -- okay. So you're asking me</p> <p>3 about the number that developed, so they're reporting</p> <p>4 33 in this. In their -- in their paper that they</p> <p>5 published they said there were 32.</p> <p>6 Q. So it actually went up from what was</p> <p>7 published in their report.</p> <p>8 A. Went up from what was published, went up</p> <p>9 one.</p> <p>10 Q. Yeah.</p> <p>11 A. It's not the file they're looking at. The</p> <p>12 total number of cases is -- in this Table 1 goes</p> <p>13 down --</p> <p>14 Q. Uh-huh.</p> <p>15 A. -- to 1065 while here it was 10 -- 1066.</p> <p>16 Q. So why did you decide to go down instead of</p> <p>17 up?</p> <p>18 A. Why did I decide to go down --</p> <p>19 Q. You report 31 infections, this document</p> <p>20 reports 33 for forced-air warming. Why did you go</p> <p>21 down?</p> <p>22 A. Oh, because -- because I tabulated the --</p> <p>23 the file that I -- that I showed you, --</p> <p>24 Q. Okay.</p> <p>25 A. -- ran that through the statistical</p>
<p style="text-align: right;">Page 146</p> <p>1 A. Yeah. I -- I -- I don't know the sources --</p> <p>2 the sources of these data. I mean it's --</p> <p>3 There's also less -- fewer subjects.</p> <p>4 Q. The source of the data is from Mr. Albrecht;</p> <p>5 is it not?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question, lack of foundation.</p> <p>8 A. Well it's -- it's based -- I gather -- well</p> <p>9 I don't know where -- where --</p> <p>10 Where is this data? Is this part of the</p> <p>11 e -- no, this is not part of the e-mail. Where does</p> <p>12 Table 1 come from in this exhibit?</p> <p>13 Q. On the prior page Mr. Reed says, "So - for</p> <p>14 clarity - this chart is the same as the one in our</p> <p>15 paper but with longer follow up?" Correct?</p> <p>16 A. "This chart," so what is this?</p> <p>17 Q. We read that earlier.</p> <p>18 A. Is this the percent of --</p> <p>19 Results.pdf, what is it? What are we</p> <p>20 looking at?</p> <p>21 Q. We're looking at the table Mr. Reed is</p> <p>22 referring to in his e-mail.</p> <p>23 A. So this is an attachment to the e-mail, --</p> <p>24 Q. Yes.</p> <p>25 A. -- is that what you're saying?</p>	<p style="text-align: right;">Page 148</p> <p>1 software, and that was the tabulation that -- that I</p> <p>2 got using SAS.</p> <p>3 Q. And this document shows otherwise.</p> <p>4 A. This document is not showing those same</p> <p>5 results, --</p> <p>6 Q. Okay.</p> <p>7 A. -- yes.</p> <p>8 MR. SACCHET: Let's take a break.</p> <p>9 THE REPORTER: Off the record, please.</p> <p>10 (Recess taken.)</p> <p>11 (Exhibit 18 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. Dr. Holford, Exhibit 18, which was</p> <p>15 previously marked as McGovern 16, is the document that</p> <p>16 you also reviewed in opining on the number of</p> <p>17 infections in the Bair Hugger study; correct?</p> <p>18 A. Yes.</p> <p>19 Q. The document is not dated; is it?</p> <p>20 A. It doesn't appear to be.</p> <p>21 Q. So you do not know when this document was</p> <p>22 finalized; correct?</p> <p>23 A. No.</p> <p>24 Q. Are you aware that Mr. McGovern never</p> <p>25 testified that this was the final data set?</p>

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<p>1 A. I don't know what he said on it.</p> <p>2 Q. You don't know one way or another whether</p> <p>3 Mr. McGovern said this was the final data set or was</p> <p>4 not the final data set.</p> <p>5 A. No, I don't.</p> <p>6 Q. You reviewed Mr. McGovern's deposition;</p> <p>7 correct?</p> <p>8 A. I did. I just don't recall his comment</p> <p>9 on -- on -- on this particular data set.</p> <p>10 Q. In the event that Mr. McGovern made no</p> <p>11 comment regarding whether or not this was the final</p> <p>12 data set, would that impact your opinion as to whether</p> <p>13 it is or is not?</p> <p>14 A. I mean I don't -- I don't know where --</p> <p>15 I mean I'm taking -- taking the data set at</p> <p>16 face value, and he is talking about it and I --</p> <p>17 it's -- so I'm assuming it -- it --</p> <p>18 Well it formed the basis of what my -- what</p> <p>19 my opinions are. That's -- this is what I -- I based</p> <p>20 it on.</p> <p>21 Q. Well in your report you say that "The</p> <p>22 results in McGovern are incorrect because they arise</p> <p>23 from an incorrect tabulation. An error is recognized</p> <p>24 in the depositions by Albrecht, Reed and McGovern."</p> <p>25 A. That there is a --</p>	<p>1 Q. Pages two and three. I don't want to spend</p> <p>2 a ton of time on this, but --</p> <p>3 A. I mean there's --</p> <p>4 Q. -- the quote is --</p> <p>5 A. I -- I -- I --</p> <p>6 Q. Can I read you the quote?</p> <p>7 A. Yes.</p> <p>8 Q. "The results by McGovern are incorrect,</p> <p>9 however, because they arise from an incorrect</p> <p>10 tabulation. An error is recognized in the depositions</p> <p>11 by Albrecht, Reed and McGovern."</p> <p>12 A. Okay. The tabulation, based on this, if you</p> <p>13 look at -- count the numbers in here, I think they</p> <p>14 agree with -- with my tabulation --</p> <p>15 Q. Okay.</p> <p>16 A. -- in -- in terms of the numbers and the</p> <p>17 dates in which these -- these occur, and so that's</p> <p>18 based on this -- this table --</p> <p>19 Q. So you --</p> <p>20 A. -- of data.</p> <p>21 Q. You're relying on the table, not Mr.</p> <p>22 McGovern's testimony -- Dr. McGovern's testimony.</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question.</p> <p>25 A. I -- I -- I -- as I say, I don't recall</p>
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<p>1 Well that's referring to not this -- not --</p> <p>2 not this exhibit, that's referring to the paper.</p> <p>3 Q. So in your --</p> <p>4 A. And so I mean an initial source of -- of --</p> <p>5 of the -- of the -- of the problem I think is -- was</p> <p>6 in Reed's testimony.</p> <p>7 Q. Okay.</p> <p>8 A. Reed testified that there was one more</p> <p>9 infection in each group.</p> <p>10 Q. We'll get there. But with respect --</p> <p>11 A. Okay.</p> <p>12 Q. -- to Mr. -- Dr. McGovern, --</p> <p>13 A. Okay.</p> <p>14 Q. -- Dr. McGovern never says anything about a</p> <p>15 tabulation error; correct?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence.</p> <p>18 A. I don't -- I don't recall exactly what</p> <p>19 doc -- what -- all of the details of -- of McGovern.</p> <p>20 Q. So you don't know whether or not he said</p> <p>21 there was a tabulation error; correct?</p> <p>22 A. I -- I don't remember.</p> <p>23 Q. Okay. Your report says that he did</p> <p>24 recognize an error; correct?</p> <p>25 A. I may have said that.</p>	<p>1 exactly where -- what McGovern said, if he says it or</p> <p>2 not, but I -- but this is a big part of where -- that</p> <p>3 forms the basis for that statement.</p> <p>4 Q. But you don't know whether or not, sitting</p> <p>5 here today, Mr. McGovern -- Dr. McGovern said that</p> <p>6 there was a tabulation error or there was not a</p> <p>7 tabulation error.</p> <p>8 A. I don't recall --</p> <p>9 Q. Okay.</p> <p>10 A. -- this morning.</p> <p>11 Q. If we could go back to the previous marked</p> <p>12 document which is McGovern Exhibit 16 --</p> <p>13 A. To which document?</p> <p>14 Q. Exhibit 18 I believe.</p> <p>15 A. Okay.</p> <p>16 MR. GORDON: Eighteen? What -- what -- just</p> <p>17 what is it?</p> <p>18 THE WITNESS: McGovern 16 --</p> <p>19 MR. SACCHET: McGovern 16 --</p> <p>20 THE WITNESS: -- which is 18.</p> <p>21 MR. SACCHET: -- which is 18.</p> <p>22 THE WITNESS: Yeah, okay.</p> <p>23 MR. GORDON: Oh.</p> <p>24 Q. Did you review any other data sets that were</p> <p>25 produced by Dr. McGovern?</p>

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<p>1 A. I don't recall --</p> <p>2 That were produced by him, no.</p> <p>3 Q. If he had produced other data sets, how do</p> <p>4 you know that this is the data set that includes the</p> <p>5 data that was published in the McGovern study?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question, assumes facts not in evidence.</p> <p>8 A. I -- I mean the whole -- the whole past of</p> <p>9 where these files came from is -- is not something</p> <p>10 that I saw.</p> <p>11 Q. You don't know where they came from.</p> <p>12 A. Well I -- I know who gave them to me.</p> <p>13 Q. Who gave them to you?</p> <p>14 A. 3M.</p> <p>15 Q. But you don't know who produced these.</p> <p>16 A. No.</p> <p>17 Q. Okay. If we turn to the very last page of</p> <p>18 this document, Exhibit 18, --</p> <p>19 A. Okay.</p> <p>20 Q. -- there is a condensed table, correct, with</p> <p>21 various fields summing through --</p> <p>22 Very last. The last page with a table on</p> <p>23 it. I think you're looking at the first --</p> <p>24 A. In my page it's Table 1.</p> <p>25 Q. The front of the document has this stamp on</p>	<p>1 Q. -- and as coded as FAW; correct?</p> <p>2 MR. GORDON: 2010.</p> <p>3 MR. SACCHET: Oh, I'm sorry. Thank you, Mr.</p> <p>4 Gordon.</p> <p>5 Q. -- 9/15/2010 and as coded as forced-air</p> <p>6 warming; correct?</p> <p>7 A. That's correct.</p> <p>8 Q. Okay. How do you know that it was</p> <p>9 incorrectly coded as to the type of device instead of</p> <p>10 the type of -- date?</p> <p>11 A. I don't know that.</p> <p>12 Q. But you're relying on the fact that this</p> <p>13 surgery in fact occurred on September 15th, 2010;</p> <p>14 correct?</p> <p>15 A. That's right.</p> <p>16 I mean if -- if the date is wrong and that</p> <p>17 date should be, you know, sometime during the Bair</p> <p>18 Hugger period, then not only the numerator would be</p> <p>19 wrong but the denominator would be wrong as well. I</p> <p>20 think the total number of cases is -- in my tabulation</p> <p>21 is the same as, I believe --</p> <p>22 Let me double check that. So 4037 --</p> <p>23 No. I'm sorry. Yeah, I'm -- I'm assuming</p> <p>24 that -- that that is -- that -- that the date is</p> <p>25 correctly -- it was based --</p>
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<p>1 it, doctor, so that's the first page.</p> <p>2 A. Oh, I see.</p> <p>3 Q. Yeah. First --</p> <p>4 It was marked, actually, on the reverse</p> <p>5 side --</p> <p>6 A. Okay.</p> <p>7 Q. -- so that's where the confusion is.</p> <p>8 If you turn to the last page, which is</p> <p>9 actually, from what I can see on your document, the</p> <p>10 one with the blue sticker on it --</p> <p>11 A. That's the one I was looking at.</p> <p>12 Q. Yeah.</p> <p>13 A. Okay. Sorry.</p> <p>14 Q. -- there are a number of fields here. I</p> <p>15 recognize it's small and I apologize for that.</p> <p>16 However, you reviewed this table; correct?</p> <p>17 A. Yes.</p> <p>18 Q. And column BJ is the date-of-surgery column;</p> <p>19 correct?</p> <p>20 A. Yes.</p> <p>21 Q. Okay.</p> <p>22 A. Appears to be, yeah.</p> <p>23 Q. And in your report you single out row 44,</p> <p>24 which has a date of surgery of 9/15/2007 --</p> <p>25 A. Yes.</p>	<p>1 My tabulation was based on the date that was</p> <p>2 given.</p> <p>3 Q. It was not based on the device coding.</p> <p>4 A. Not the --</p> <p>5 No.</p> <p>6 Q. And if you could --</p> <p>7 We're going to toggle back between two</p> <p>8 different documents, so --</p> <p>9 A. Okay.</p> <p>10 Q. I don't want you to get too mixed up here,</p> <p>11 but if you can go back to the McGovern study which we</p> <p>12 had marked as Exhibit 13 in this deposition --</p> <p>13 A. Okay.</p> <p>14 Q. -- and pull that out.</p> <p>15 A. Okay.</p> <p>16 Q. And I just want you to hold Fig. 7, which is</p> <p>17 in the back end of the McGovern study, next to the</p> <p>18 table in front of you. So you can just pull up Fig.</p> <p>19 7 in the McGovern study.</p> <p>20 MR. GORDON: And what is --</p> <p>21 What are we holding it next to?</p> <p>22 Q. Just simply if you can pull up Fig. 7 and</p> <p>23 put it down and have the table that we just marked</p> <p>24 from McGovern Exhibit 16 next to it.</p> <p>25 Yup, you got it. Okay. Yeah. And let's --</p>

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<p style="text-align: right;">Page 157</p> <p>1 You have to hold them there.</p> <p>2 A. Okay.</p> <p>3 Q. I recognize that this is a hypothetical, but</p> <p>4 in the event that row 44 in this table, --</p> <p>5 A. Uh-huh.</p> <p>6 Q. -- if that infection had actually occurred</p> <p>7 in September of 2008, that would be in the Bair Hugger</p> <p>8 period; correct?</p> <p>9 A. Yes. Yeah.</p> <p>10 Q. Okay. Have you ever created a graph like</p> <p>11 Fig. 7 before?</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question.</p> <p>14 A. No.</p> <p>15 Q. Okay. But you understand that the X axis is</p> <p>16 a range of dates and the Y axis is the percent of</p> <p>17 infection; correct?</p> <p>18 A. Well it -- it depends on which axis you're</p> <p>19 looking at. It's the number -- it's -- there's a --</p> <p>20 There is a left and a right axis.</p> <p>21 Q. Okay. The horizontal line on the bottom of</p> <p>22 the graph goes from July 2008 to January 2011; right?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And there's a number of data points</p> <p>25 in this graph and some are on the top and some are on</p>	<p style="text-align: right;">Page 159</p> <p>1 A. Yes.</p> <p>2 Q. -- that's the manner in which you would have</p> <p>3 to represent it on the graph; correct?</p> <p>4 A. My -- my assumption is -- is the jitter has</p> <p>5 to do with the vertical jitter. They vertically</p> <p>6 jittered it and not -- so the -- so the date --</p> <p>7 It appears on the right date, --</p> <p>8 Q. Yup.</p> <p>9 A. -- it's just the no-infection point is sort</p> <p>10 of -- and they jittered both the no infections and the</p> <p>11 infections. If you notice, they're not all exactly</p> <p>12 the same points, so they --</p> <p>13 Q. Well let me put it this way: If you were</p> <p>14 going to put these dots on this graph, --</p> <p>15 A. Yeah.</p> <p>16 Q. -- you wouldn't be able to put them in the</p> <p>17 right location if you were just saying is it infection</p> <p>18 or is it non-infection; right? You need to consider</p> <p>19 the date of the infection or non-infection; right?</p> <p>20 A. Yeah, it's -- it's by the date, yeah.</p> <p>21 Q. So the date is the way in which you</p> <p>22 determine where each infection or non-infection goes</p> <p>23 on the graph.</p> <p>24 A. Uh-huh.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 158</p> <p>1 the bottom; correct?</p> <p>2 A. Yeah.</p> <p>3 Q. And based on the axis on the right-hand</p> <p>4 side, those on the bottom designate no infection and</p> <p>5 those on the top designate infection; correct?</p> <p>6 A. Correct.</p> <p>7 Q. And the legend for Fig. 7 notes that the</p> <p>8 data points have been jittered to avoid overprinting;</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. And my understanding of that is essentially</p> <p>12 that when you look at the graph, there could be two</p> <p>13 data points that have similar times, but you don't put</p> <p>14 them on top of each other because it would just look</p> <p>15 like one point; is that correct?</p> <p>16 A. That's right. They're trying to see it. I</p> <p>17 mean in the Xerox you kind of lose it, but --</p> <p>18 Q. Okay.</p> <p>19 A. Yeah. Yeah.</p> <p>20 Q. And if you were to attempt to re-create this</p> <p>21 graph --</p> <p>22 A. Uh-huh?</p> <p>23 Q. -- in a similar way that you recalculated</p> <p>24 the data in the study, because each jittered data</p> <p>25 point is specific to a date, --</p>	<p style="text-align: right;">Page 160</p> <p>1 THE REPORTER: Your answer? Your answer?</p> <p>2 THE WITNESS: Yes.</p> <p>3 Q. Okay. Have you compared this graph to</p> <p>4 Exhibit 18 in this case but was previously marked as</p> <p>5 Exhibit 16 by McGovern in -- in the McGovern</p> <p>6 deposition, have you done this side-by-side comparison</p> <p>7 before?</p> <p>8 A. No.</p> <p>9 Q. Okay. So I'm going to walk you through this</p> <p>10 and I'll do my best to do it slowly, but the first</p> <p>11 infection data point that we have in Fig. 7 of the</p> <p>12 McGovern study appears to be July 2008; correct?</p> <p>13 Right on the beginning of the study period in the</p> <p>14 graph of Fig. 7, the first data point in the infection</p> <p>15 area.</p> <p>16 A. First infection. I guess so.</p> <p>17 Q. Yeah. And if you go to McGovern 16, the</p> <p>18 first infection, which is row six, the date of surgery</p> <p>19 is July 1st, 2008; correct?</p> <p>20 A. That's right.</p> <p>21 Q. So that data point matches this date in</p> <p>22 McGovern 16; correct?</p> <p>23 A. Okay.</p> <p>24 Q. Do you agree?</p> <p>25 A. Yeah, it seems to be.</p>

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<p>1 Q. Yeah. Okay.</p> <p>2 A. Yeah.</p> <p>3 Q. Now looking at the table, the next three</p> <p>4 infections are August 7, 2008, August 12, 2008 and</p> <p>5 August 13, 2008; correct?</p> <p>6 A. Yes.</p> <p>7 Q. In McGovern 16 --</p> <p>8 Which we've marked as Exhibit 18; correct?</p> <p>9 A. Right.</p> <p>10 Q. -- do you see the cluster of three jittered</p> <p>11 data points in the infection area of this graph?</p> <p>12 A. Yes.</p> <p>13 Q. That appears to align with those three</p> <p>14 infections; correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. The next cell in McGovern 16 is</p> <p>17 September 30th, 2008; correct?</p> <p>18 A. Yeah.</p> <p>19 Q. And the infection after that is November</p> <p>20 4th, 2008; correct?</p> <p>21 In the cell.</p> <p>22 A. Yeah.</p> <p>23 Q. Okay. So that's a gap of about a month and</p> <p>24 five days, September --</p> <p>25 A. Yeah.</p>	<p>1 A. I didn't say that. I --</p> <p>2 Q. So you don't know that McGovern 16 is the</p> <p>3 final data set.</p> <p>4 A. No, I don't.</p> <p>5 Q. Okay.</p> <p>6 A. But I mean it seems plausible.</p> <p>7 MR. GORDON: Counsel, counsel --</p> <p>8 A. It's hard to sort of compare here because</p> <p>9 this axis is -- you know, the cut points are --</p> <p>10 Q. Yeah.</p> <p>11 A. -- six months --</p> <p>12 Q. I understand. I just wanted to clarify</p> <p>13 that.</p> <p>14 A. Yeah.</p> <p>15 MR. GORDON: Counsel, I just want -- want to</p> <p>16 let you know I have e-mailed to you and Ms. Conlin the</p> <p>17 Augustine Bates number 0005277 --</p> <p>18 MR. SACCHET: I know.</p> <p>19 MR. GORDON: -- that seems to have been</p> <p>20 missing in the copy which you -- you marked as Exhibit</p> <p>21 14.</p> <p>22 MR. SACCHET: Okay.</p> <p>23 MR. GORDON: I don't know if it's a</p> <p>24 photocopy error or whatever, but anyway, you do have</p> <p>25 access to it. I can call it up on my iPad if you want</p>
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<p>1 Q. -- 30th to November 4th; correct?</p> <p>2 A. It is, yeah.</p> <p>3 Q. Okay. Now let's go to the graph. There are</p> <p>4 two points in a horizontal line virtually on top of</p> <p>5 each other; correct?</p> <p>6 A. Yeah.</p> <p>7 Q. One of those points must be the September</p> <p>8 30th data point; correct? Because that's the next</p> <p>9 infection in the table and that's the next infection</p> <p>10 reported in the graph.</p> <p>11 A. It could be. I mean it's -- now you're</p> <p>12 sort of --</p> <p>13 Q. Well I mean it --</p> <p>14 A. It's hard to tell. The -- the axis is so</p> <p>15 rough it's a little hard to tell exactly, but it seems</p> <p>16 plausible.</p> <p>17 Q. I mean if the prior three infections are the</p> <p>18 cluster of three, which are all August infections, --</p> <p>19 A. Yeah.</p> <p>20 Q. -- the next data point must be September,</p> <p>21 correct, and that's the next infection in the McGovern</p> <p>22 16 Excel file.</p> <p>23 A. It could be, yeah.</p> <p>24 Q. You're saying that McGovern 16 is the final</p> <p>25 data set; correct?</p>	<p>1 to look at it.</p> <p>2 MR. SACCHET: I'm not -- I'm not there right</p> <p>3 now, but I appreciate it, Mr. Gordon.</p> <p>4 MR. GORDON: But in fairness, there are no</p> <p>5 infections listed on that.</p> <p>6 MR. SACCHET: I appreciate your testimony.</p> <p>7 MR. GORDON: Well it stands in contrast to</p> <p>8 you giving him an exhibit missing a page and implying</p> <p>9 that there was something on that page that maybe, you</p> <p>10 know, was a September 15th, 2008 --</p> <p>11 MR. SACCHET: I'm talking about McGovern 16</p> <p>12 right now.</p> <p>13 MR. GORDON: I -- I was --</p> <p>14 No, you were talking about --</p> <p>15 MR. SACCHET: I wasn't talking at all about</p> <p>16 this.</p> <p>17 MR. GORDON: But -- but you set this whole</p> <p>18 thing up with a missing page --</p> <p>19 MR. SACCHET: That's how it was produced.</p> <p>20 MR. GORDON: I don't know if that was how it</p> <p>21 was produced or not.</p> <p>22 MR. SACCHET: Ask DFT.</p> <p>23 MR. GORDON: Pardon?</p> <p>24 MR. SACCHET: Ask DFT if that's the final</p> <p>25 copy.</p>

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<p>1 MR. GORDON: Well then maybe DFT screwed up.</p> <p>2 I don't know. But you now have --</p> <p>3 MR. SACCHET: Thank you.</p> <p>4 MR. GORDON: -- 5277 --</p> <p>5 MR. SACCHET: Great.</p> <p>6 MR. GORDON: -- in your e-mail and it shows</p> <p>7 no infection.</p> <p>8 MR. SACCHET: I'll note for the record the</p> <p>9 two-minute soliloquy by Mr. Gordon as a speaking</p> <p>10 objection that should be not raised in any deposition</p> <p>11 of an expert witness in this litigation.</p> <p>12 Q. Back to McGovern 16 -- which is actually the</p> <p>13 document that we were speaking about, not Albrecht</p> <p>14 Exhibit 10 -- you stated you don't know whether</p> <p>15 McGovern 16 is the final data set, but I want to draw</p> <p>16 your attention back to the graph, and there are two</p> <p>17 dots there; correct?</p> <p>18 A. Right.</p> <p>19 Q. And they're on top of each other; correct?</p> <p>20 A. Yes.</p> <p>21 Q. And if the infection cell in the McGovern</p> <p>22 table was from 9/30/2009 and that's the next</p> <p>23 infection, the second data point in the graph should</p> <p>24 be from a similar time period; correct?</p> <p>25 A. So where are you now?</p>	<p>1 A. Okay.</p> <p>2 Q. And the next infection is not until November</p> <p>3 4th --</p> <p>4 A. Yeah.</p> <p>5 Q. -- in McGovern 16; correct?</p> <p>6 A. Right.</p> <p>7 Q. And the one after that's November 7th --</p> <p>8 A. Yeah.</p> <p>9 Q. -- and the one after that's November 18th;</p> <p>10 right?</p> <p>11 A. Right.</p> <p>12 Q. Do you see the cluster of three data</p> <p>13 points --</p> <p>14 A. Yeah.</p> <p>15 Q. -- after the two?</p> <p>16 A. Yes.</p> <p>17 Q. Those are presumably the November cluster of</p> <p>18 infections; correct?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question, lack of foundation.</p> <p>21 A. I don't know for sure. It --</p> <p>22 Q. It appears to be.</p> <p>23 A. It's plausible.</p> <p>24 Q. Okay. What is the second date -- the second</p> <p>25 dot in between the cluster of three on the right and</p>
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<p>1 Q. Okay. So I'm still on the one we were</p> <p>2 talking about, before I was interrupted about a</p> <p>3 different exhibit, which is row 10 with the September</p> <p>4 30th, 2008 infection. Do you see that?</p> <p>5 A. Right. Uh-huh.</p> <p>6 Q. Okay. And the next infection isn't until</p> <p>7 November 4th, 2008; correct?</p> <p>8 A. That's right.</p> <p>9 Q. And that's about a month-long gap; right?</p> <p>10 A. Right.</p> <p>11 Q. But in the graph we have two dots --</p> <p>12 A. Yeah.</p> <p>13 Q. -- right on top of each other, one of which</p> <p>14 you said is plausibly the September 30th, 2008</p> <p>15 infection; correct?</p> <p>16 A. Septem --</p> <p>17 You're -- you're -- you're talking about</p> <p>18 number 10?</p> <p>19 Q. Yup. It's September 30th, 2008; correct?</p> <p>20 A. It's September 30. Okay.</p> <p>21 Q. Okay.</p> <p>22 A. So that's one of the --</p> <p>23 Q. That's one of those two.</p> <p>24 A. -- two.</p> <p>25 Q. Yeah.</p>	<p>1 the cluster of three on the left that's paired with</p> <p>2 the September 30th, 2008 infection?</p> <p>3 A. I don't know.</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question.</p> <p>6 Q. It's not in the McGovern 16 table; is it?</p> <p>7 MR. GORDON: Lack of foundation.</p> <p>8 A. I -- I don't know what formed this graph. I</p> <p>9 don't -- I mean --</p> <p>10 Q. This is the graph that's reported in the</p> <p>11 published study; correct?</p> <p>12 A. It is a graph in the -- in the published</p> <p>13 study, --</p> <p>14 Q. Yeah. I mean --</p> <p>15 A. -- but the data that went -- that formed</p> <p>16 this graph I do not -- I don't know that I've seen.</p> <p>17 It doesn't seem to be this table.</p> <p>18 Q. Yeah. So it's -- this --</p> <p>19 This jittered data point is not in McGovern</p> <p>20 16.</p> <p>21 A. It doesn't appear to be.</p> <p>22 Q. And this jit -- jittered data point is in</p> <p>23 2008.</p> <p>24 A. It --</p> <p>25 Yeah, it does seem to be in 2008.</p>

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<p style="text-align: right;">Page 169</p> <p>1 Q. That's during the Bair Hugger warming 2 period; correct? 3 A. Uh-huh. 4 Q. So there appears to be an additional 5 jittered data point in the 2008 Bair Hugger period 6 that is not reflected on the McGovern 16 -- 7 A. Yeah. Yeah. 8 Q. -- file. 9 A. Yeah. 10 MR. GORDON: Object to the form of the 11 question, lack of foundation. 12 Q. And if you take away cell 44 for the sake of 13 argument and you add in the data point that we just 14 discussed, which is in the Bair Hugger period from 15 2008, that gives you 32 infections. 16 MR. GORDON: Object to the form of the 17 question, lack of foundation, in -- incomplete 18 hypothetical. 19 A. So I don't under -- 20 Q. I can break it down further if you want. 21 A. Yeah. What exactly are you proposing? 22 Q. Okay. So in your report you say cell 44 was 23 miscoded to be -- 24 A. Yeah. 25 Q. -- a forced-air warming infection because</p>	<p style="text-align: right;">Page 171</p> <p>1 AFTERNOON SESSION 2 BY MR. SACCHET: 3 Q. Dr. Holford, I should ask, do you prefer 4 going by doctor or professor? 5 A. Professor is fine. Either one. 6 Q. Okay. In your report on page two you also 7 reference the testimony of Dr. Reed; correct? 8 A. Yes. 9 Q. And you state that the published McGovern 10 analysis may have been in error in light of that 11 testimony; correct? 12 A. Yes. 13 Q. And that testimony suggested that there may 14 have been an additional infection both in the Bair 15 Hugger arm and in the Hot Dog arm; correct? 16 A. That's correct. 17 Q. And you also perform a calculation in 18 footnote one of your report that states, "Even if one 19 assumes that Dr. Reed's recollection in his deposition 20 was correct (that there was one additional infection 21 in each group), the odds ratio is nevertheless 22 markedly different than reported in the published 23 paper," and you go on to note that the odds ratio 24 would be 2.86 with a significant p-value of .0356; 25 correct?</p>
<p style="text-align: right;">Page 170</p> <p>1 the date of infection -- or date of operation was 2 September 15, 2010; right? 3 A. Yes. 4 Q. So if we just take that off the table, we're 5 down to the 31 infections that you assume in your 6 report; correct? 7 A. Yes. 8 Q. Okay. And this jittered data point in 2008 9 is not reflected in McGovern 16. That's what you just 10 testified to. 11 A. It doesn't seem to be. 12 Q. Okay. If we add that data point into this 13 graph, there are 32 infections. 14 A. Okay. Yes. 15 Q. Thank you. 16 MR. SACCHET: We'll take a break. 17 THE REPORTER: Off the record, please. 18 (Luncheon recess taken.) 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 172</p> <p>1 A. That's correct. 2 Q. Do you have any reason for not relying on 3 Dr. Reed's recollection of one additional infection in 4 each arm versus the Albrecht Exhibit 10 and McGovern 5 Exhibit 16? 6 A. No. I was just taking what -- 7 You know, it's just based on what he said -- 8 Q. You would agree that -- 9 A. -- in his deposition. 10 Q. Are you finished? 11 A. Yes. 12 Q. You would agree that the calculations that 13 you have performed that are within your report rely on 14 McGovern 16 and Albrecht Exhibit 10; correct? 15 A. I think all of the rest of the calculations, 16 other than footnote one, are based on 10 and 16. 17 Q. And you recognize that Mr. Reed's testimony 18 and the cal -- and the calculation you performed based 19 on that testimony has a higher odds ratio of 2.86 than 20 the 2.76 that you used throughout the report, which 21 are based on Albrecht 10 and McGovern 16. 22 A. That's right. 23 Q. So it's possible that in fact the OR of 2.86 24 could be the actual odds ratio of the study. 25 A. Yes. There seems to be some error in the</p>

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<p style="text-align: right;">Page 173</p> <p>1 tabulation in the -- in the paper is what -- what 2 seems to be implied by this testimony of, you know, 3 Reed and Albright and -- and whatever, so I'm trying 4 to sort out as best I can what that error is. 5 Q. And you would agree that the calculation you 6 performed as to Mr. Reed's testimony contradicts the 7 calculation you performed with respect to the McGovern 8 Exhibit 16 and Albrecht Exhibit 10 data; correct? 9 A. It -- it is different, yes. 10 Q. And the Reed calculation results in a 11 significant p-value; correct? 12 A. That's right. 13 Q. To be specific, the calculation on page two 14 of your report where you derive a p-value -- or an 15 odds ratio of 2.76 derives from McGovern Exhibit 16 16 and Albrecht Exhibit 10; correct? 17 A. That's correct. 18 Q. To also be clear, the time trend data which 19 you discuss on page four of your report also derives 20 from Albrecht Exhibit 10 and McGovern Exhibit 16; 21 correct? 22 A. That's correct. 23 Q. The reanalysis of the Jensen data that you 24 performed on page five of your report also depends on 25 the veracity of McGovern Exhibit 16 and Albrecht</p>	<p style="text-align: right;">Page 175</p> <p>1 Q. I'm going to change gears a little bit now 2 and talk about the particular tests that -- 3 statistical tests that were used both in the McGovern 4 study and in your report. 5 A. Uh-huh. 6 Q. With respect to -- with respect to reviewing 7 the McGovern study, the authors used chi-squared; 8 correct? 9 A. That's correct. 10 Q. And their calculation, when using the data 11 reported in this study, resulted in a p-value of .024; 12 correct? 13 A. I think that's correct. That sounds -- 14 sounds right. I'd have to look back at the paper, but 15 I think it's right. 16 Q. Okay. It is, but -- 17 And based on the chi-squared on that data 18 set, the odds ratio is 3.8. 19 A. That's right. 20 Q. And the confidence interval was 1.2 to 12.5; 21 correct? 22 A. That's right. 23 Q. Now in your report you also apply Fisher's 24 exact test to the data that was reported in the 25 McGovern study; correct?</p>
<p style="text-align: right;">Page 174</p> <p>1 Exhibit 10. 2 A. That's correct. 3 Q. The calculation you performed on page four 4 with respect to controlling for the thromboprophylaxis 5 also derives from Albrecht Exhibit 10 and McGovern 6 Exhibit 16; correct? 7 A. Correct. 8 MR. GORDON: Object to the form of the 9 question. 10 Q. The calculation you performed also on page 11 six with respect to controlling for the antibiotic 12 derives from the data in McGovern Exhibit 16 and 13 Albrecht Exhibit 10; correct? 14 A. Yes. 15 Q. And finally, with respect to the conclusions 16 that you offer in terms of causal inferences in the 17 latter parts of your report, those calculations so too 18 rely on the data from McGovern Exhibit 16 and Albrecht 19 Exhibit 10; correct? 20 A. Yes. They're basically referring to the 21 analyses I did in the previous sections. 22 Q. So all those calculations depend on the 23 veracity of Albrecht Exhibit 10 and McGovern Exhibit 24 16. 25 A. Yes, I think that's right. Yeah.</p>	<p style="text-align: right;">Page 176</p> <p>1 A. Yes, I did. 2 Q. And when you perform that calculation, you 3 also find a significant p-value; correct? 4 A. That's correct. 5 Q. And the p-value with respect to the reported 6 data using Fisher's is .0176; correct? 7 A. That's correct. Yeah. 8 Q. So I've been trying to figure this out 9 because I know that Fisher's exact is generally a more 10 conservative test, but in this particular instance 11 chi-squared had a less significant p-value but which 12 was still significant than under Fisher. Is that -- 13 And I can back up. The p-value using X 14 chi-squared was .024 in the study; correct? 15 A. That's right. 16 Q. And then when you did Fisher's on the -- the 17 data reported in this study, you got a p-value of 18 .07 -- .0176. 19 A. Yeah. 20 Q. So in that particular instance the p-value 21 actually increased by using chi-squared; correct? 22 A. It -- it did. The Fisher's -- but I -- 23 The premise I think of your question was 24 that Fisher's is conservative. 25 Q. And we can get to that later.</p>

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<p>1 A. Oh, okay. I would disagree with that --</p> <p>2 Q. Okay.</p> <p>3 A. -- characterization.</p> <p>4 Q. But with respect to what we're talking about</p> <p>5 now, the p-val -- p-value actually went down when</p> <p>6 using Fisher's as opposed to chi-squared.</p> <p>7 A. That's correct.</p> <p>8 Q. If the authors had truly wanted to cherry</p> <p>9 pick a p-value, they could have employed Fisher's and</p> <p>10 had a more significant p-value; correct?</p> <p>11 A. They -- they could have, yes.</p> <p>12 Q. And they did not.</p> <p>13 A. No.</p> <p>14 Q. When using Fisher's on the original data set</p> <p>15 reported in the McGovern study, the OR, instead of</p> <p>16 being 3.8, is 3.79, correct, so virtually identical?</p> <p>17 A. Yeah, uh-huh. I assume it just depends on</p> <p>18 how much --</p> <p>19 What you're rounding is I think the</p> <p>20 difference.</p> <p>21 Q. Okay. Now going back to the data that you</p> <p>22 used in your report; namely, the four infections in</p> <p>23 the Hot Dog period and the 31 infections in the Bair</p> <p>24 Hugger period, --</p> <p>25 A. Uh-huh.</p>	<p>1 p-values, the chi-square one or the --</p> <p>2 Q. The chi-squared P&L value of .0480 --</p> <p>3 A. Okay.</p> <p>4 Q. -- is the same p-value that Jensen et al</p> <p>5 reported in their study, which evaluated whether there</p> <p>6 was an increased risk of infection between using</p> <p>7 Xarelto versus using a low-molecular-weight heparin.</p> <p>8 A. I don't remember what they -- exactly what</p> <p>9 they reported.</p> <p>10 (Exhibit 19 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. SACCHET:</p> <p>13 Q. Exhibit 19 is entitled "Return to theatre</p> <p>14 following total hip and knee replacement, before and</p> <p>15 after the introduction of rivaroxaban," by Jensen et</p> <p>16 al; correct?</p> <p>17 A. Yes. And where are you --</p> <p>18 Q. In the abstract on the first page in the</p> <p>19 second paragraph, the statement there says, "Nine</p> <p>20 patients in the control (tinzaparin) group returned to</p> <p>21 theatre with wound complications within 30 days,</p> <p>22 compared with 22 patients in the rivaroxaban group.</p> <p>23 This increase was statistically significant (at p</p> <p>24 equals 0.048)."</p> <p>25 MR. GORDON: Counsel, I think your earlier</p>
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<p>1 Q. -- you also used that data and calculated</p> <p>2 p-values and odds ratios using chi-squared; correct?</p> <p>3 A. For the analysis on --</p> <p>4 Let's see, where is it?</p> <p>5 Q. Page two.</p> <p>6 A. Page two. I mean the p-value I give there</p> <p>7 is -- is actually the F -- I'm sorry, Fisher's --</p> <p>8 Fisher's exact.</p> <p>9 Q. Did you report a p-value of .0480 when using</p> <p>10 chi-squared --</p> <p>11 A. Oh, I'm sorry.</p> <p>12 Q. -- on the remixed data set?</p> <p>13 A. That's true. I also -- I also did the</p> <p>14 chi-square in the --</p> <p>15 Yeah, it got a little lower.</p> <p>16 Q. And you note that it is just below the</p> <p>17 threshold of statistical significance; correct?</p> <p>18 A. That's right.</p> <p>19 Q. It's the same p-value that was reported in</p> <p>20 the Jensen study which you cited in your reference</p> <p>21 material; correct?</p> <p>22 MR. GORDON: Which -- which is?</p> <p>23 THE WITNESS: Which --</p> <p>24 MR. SACCHET: The Jensen study on control --</p> <p>25 MR. GORDON: No, which -- which of the</p>	<p>1 question was that they reported a statistically</p> <p>2 significant difference in infection rates at that</p> <p>3 p-value, that's -- and that's not what they did.</p> <p>4 Q. I'll rephrase my question.</p> <p>5 A. They didn't -- yeah.</p> <p>6 Q. I'll rephrase the question.</p> <p>7 Is the p-value that's reported in the</p> <p>8 abstract of the Jensen study 0.048?</p> <p>9 I recognize that the 8 is difficult to read.</p> <p>10 A. It's hard to see if it's an 8 or a 6, but</p> <p>11 yeah, it's -- it's less than .05.</p> <p>12 Q. Okay. And the authors there deemed it to be</p> <p>13 statistically significant.</p> <p>14 MR. GORDON: What --</p> <p>15 A. That's right.</p> <p>16 Q. They made no mention that it was marginally</p> <p>17 significant or close to the threshold of significance.</p> <p>18 A. They didn't say.</p> <p>19 Q. So whether or not one uses the original data</p> <p>20 as reported in the McGovern study or the reanalyzed</p> <p>21 data that you provide in your report, --</p> <p>22 A. Uh-huh?</p> <p>23 Q. -- using X-squared results in a significant</p> <p>24 p-value; correct? Under .05.</p> <p>25 A. That's right, yeah.</p>

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<p style="text-align: right;">Page 181</p> <p>1 Q. You go on in your report, however, to state</p> <p>2 that Fisher's exact test is the more appropriate test</p> <p>3 in this circumstance; correct, professor?</p> <p>4 A. Uh-huh.</p> <p>5 THE REPORTER: Your answer?</p> <p>6 THE WITNESS: Yes. Yeah.</p> <p>7 Q. Notwithstanding your view as to the</p> <p>8 propriety of Fisher's versus chi-squared, you'd</p> <p>9 agree that there is a long-standing debate about</p> <p>10 whether to use Fisher's or chi-squared based on</p> <p>11 certain determinants such as sample size and incidence</p> <p>12 of an outcome; correct?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question.</p> <p>15 A. I -- I don't know that there's a debate. I</p> <p>16 think it's -- Fisher's is -- is --</p> <p>17 I mean chi-square de -- derives from a -- a</p> <p>18 mathematical approximation for what the distribution</p> <p>19 is for the statistic that you're looking at, and so</p> <p>20 it's relying on that approximation. The approximation</p> <p>21 works quite well if the sample size is large, it works</p> <p>22 more poorly as the -- as the expected number of cases</p> <p>23 becomes smaller and smaller. And so it -- it's in --</p> <p>24 In contrast, the Fisher's exact test is not</p> <p>25 an approximation, it's an exact calculation.</p>	<p style="text-align: right;">Page 183</p> <p>1 the --</p> <p>2 The direction does not go one way. I mean</p> <p>3 as you -- as you --</p> <p>4 Q. Yeah.</p> <p>5 A. -- just pointed out, --</p> <p>6 Q. It can go down.</p> <p>7 A. -- Fisher's can -- can be greater or less,</p> <p>8 and the context in which I used Fisher's is that I</p> <p>9 think it's more accurate when the numbers are small</p> <p>10 and -- as in these tables.</p> <p>11 Q. I'll get to that in a moment. I just want</p> <p>12 to pin down --</p> <p>13 A. Sure.</p> <p>14 Q. -- that there are statisticians who have</p> <p>15 criticized Fisher's exact test as being overly</p> <p>16 conservative.</p> <p>17 A. Okay.</p> <p>18 Q. You agree.</p> <p>19 A. There may be a few that -- that don't agree,</p> <p>20 but --</p> <p>21 Q. Do you know Professor Douglas Liddell of</p> <p>22 McGill University?</p> <p>23 A. I know of him, yeah.</p> <p>24 Q. Have you read "Practical Tests of 2 x 2</p> <p>25 Contingency Tables" that was published in The</p>
<p style="text-align: right;">Page 182</p> <p>1 That's -- so because -- depending on the --</p> <p>2 You know, if results that go into that</p> <p>3 are -- are appropriate, then you're getting a -- an</p> <p>4 actual p-value and not an approximate p-value, which</p> <p>5 is what the chi-square is -- chi-square is yielding,</p> <p>6 so in that respect I don't know that there's a huge</p> <p>7 debate or controversy about that. The only --</p> <p>8 Chi-square is a lot easier to compute, and</p> <p>9 so when you're doing it by hand it's a lot more work</p> <p>10 to do Fisher's, but if you're just typing in the table</p> <p>11 into a -- into a computer, which of course is what we</p> <p>12 have now, it's pretty straightforward to do.</p> <p>13 Q. But you're aware that other statisticians</p> <p>14 have criticized Fisher's exact test as being overly</p> <p>15 conservative; are you not?</p> <p>16 A. I'm not sure it's particularly overly --</p> <p>17 overly conservative.</p> <p>18 Q. Not in your view. I'm saying are you --</p> <p>19 A. Yes.</p> <p>20 Q. -- aware of other statisticians who have</p> <p>21 criticized Fisher's exact test as being overly</p> <p>22 conservative?</p> <p>23 A. Some might argue that, yeah.</p> <p>24 Q. So there is a --</p> <p>25 A. It -- it's not -- but it's not uniformly --</p>	<p style="text-align: right;">Page 184</p> <p>1 Statistician in 1976?</p> <p>2 A. Ooh, I don't know. I may have at some</p> <p>3 point. I don't remember.</p> <p>4 Q. So you're not aware one way or the other</p> <p>5 whether Professor Liddell said Fisher's exact test was</p> <p>6 overly conservatively in that article.</p> <p>7 A. He may well have. I'm not -- just -- I just</p> <p>8 don't recall that paper off the top of my head.</p> <p>9 Q. He's an expert in the field; correct?</p> <p>10 A. Yeah, uh-huh.</p> <p>11 Q. I assume you're also aware of Professor --</p> <p>12 or Dr. Joseph Berkson from the Mayo Clinic in</p> <p>13 Minneapolis.</p> <p>14 A. Yes.</p> <p>15 Q. He was the head of biometry at the Mayo</p> <p>16 Clinic?</p> <p>17 A. Yes.</p> <p>18 Q. Same field as you; right?</p> <p>19 A. That's right.</p> <p>20 Q. And the Mayo Clinic is a well-respected</p> <p>21 institution; correct?</p> <p>22 A. Yes.</p> <p>23 Q. You respect Professor Berkson's views?</p> <p>24 A. Basically, yeah. I mean, yeah, he was there</p> <p>25 a while ago.</p>

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<p>1 Q. Have you read his article and his praises of 2 the exact test?</p> <p>3 A. I -- I may have. I don't remember. When 4 was that published?</p> <p>5 Q. I actually don't know when it was published. 6 I think it was in the '80s.</p> <p>7 A. Okay.</p> <p>8 Q. But are you aware of his conclusion that the 9 use of the term "Fisher's exact" is simply just a 10 sobriquet because it derives from R. A. Fisher's 11 creation of the test?</p> <p>12 A. That's -- that's a --</p> <p>13 Yeah. Fisher I know derived the test and --</p> <p>14 Q. But the use of the word "exact" really -- I 15 mean is a sobriquet.</p> <p>16 A. Well the --</p> <p>17 I suppose. I mean it's exact if -- if -- 18 depending on the results that Fisher -- that form the 19 basis for -- for Fisher's derivation. I mean it's 20 a --</p> <p>21 It is based on a hypergeometric distribution 22 and it's exact from that. The chi-square by 23 comparison is based on the idea that -- you know, that 24 it becomes approximately a chi-square distribution, so 25 there's an approximation involved with that. And why</p>	<p>1 Q. And that's a problem with Fisher's test.</p> <p>2 A. I don't know if it's a problem. It's --</p> <p>3 Q. It's a ramification of the test.</p> <p>4 A. It's an issue, yes.</p> <p>5 Q. Okay. And in light of that, according to 6 Berkson, Fisher's may result in the rejection of 7 p-values that are very close to significant but 8 ultimately render them non-significant.</p> <p>9 A. That's right. Yeah. You could -- you could 10 have that.</p> <p>11 Q. So in this --</p> <p>12 A. So in the example I just stated, I mean it 13 could be if that's the situation involved, you would 14 only reject at the .04, and so there's that little --</p> <p>15 Q. Yeah.</p> <p>16 A. -- gap.</p> <p>17 Q. Isn't that precisely the circumstance here, 18 because when you analyzed the remixed data using 19 chi-squared, you calculated a p-value of 0.0480; 20 correct?</p> <p>21 A. I guess that's what it was, yeah.</p> <p>22 Q. And then when you used Fisher, it went to 23 0.0507, so it took -- it took a p-value --</p> <p>24 A. Yes.</p> <p>25 Q. -- that was significant, just below the</p>
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<p>1 he called it an exact test is because there was not an 2 approximation involved.</p> <p>3 Q. Do you disagree with Professor Berkson's 4 view that the problem with Fisher's is that you're 5 essentially combining discrete statistics with fixed 6 significance levels -- significance levels?</p> <p>7 A. Well I think -- yeah. I mean that -- that 8 is a problem. That is, I think, a different -- 9 different problem because it is discrete. If you're 10 comparing at exactly the .05 level, the discrete 11 probabilities that it can take may not correspond to 12 exactly the .05.</p> <p>13 Q. Yeah.</p> <p>14 A. So it may go from .04 to .06, so you'd 15 reject the .04 but not the .06.</p> <p>16 Q. That's a problem.</p> <p>17 A. There's a space in there, so there is -- 18 there is a little bit of an ambiguity there. It 19 may --</p> <p>20 Well not it's ambiguous. It's either less 21 or not.</p> <p>22 Q. Yeah.</p> <p>23 A. But there is -- there is a bit of a -- of 24 a -- of a problem of comparing exactly because it's 25 not a continuous distribution.</p>	<p>1 traditional threshold of 0.05, and it rendered it non- 2 significant using Fisher's. That's exactly what 3 Berkson describes in his article of -- in his praise 4 of the exact test; correct?</p> <p>5 A. As I say, I don't remember what -- what 6 Berkson -- Berkson's issue was. If that was his 7 issue, that would be an issue, and that, I mean --</p> <p>8 Q. That's the issue we just talked about when 9 you said --</p> <p>10 A. Yeah, yeah. That -- that is -- that is an 11 issue --</p> <p>12 Q. Okay.</p> <p>13 A. -- associated with that test. I mean any 14 way you cut it, it's very close to the line. Even -- 15 even the chi-square was, what, point -- .048.</p> <p>16 Q. Yeah.</p> <p>17 A. That's not way out in the wild blue yonder 18 somewhere, that's really -- that is close to the line, 19 too.</p> <p>20 Q. Agreed.</p> <p>21 A. They're both, you know, close to the line.</p> <p>22 Q. But in your conclusions of your report, one 23 of your rationales for concluding that the McGovern 24 study is not valid is because the p-value is not 25 significant; correct?</p>

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<p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 A. That the p-value --</p> <p>4 Well it is what it is.</p> <p>5 Q. Well on page six of your --</p> <p>6 A. I mean --</p> <p>7 Q. -- report in the "Conclusions regarding the</p> <p>8 McGovern et al. findings" you say, "Reasons why the</p> <p>9 McGovern et al. conclusions are not valid are:</p> <p>10 "1." And the very last clause of that</p> <p>11 number one is, "...which is close but not</p> <p>12 statistically significant."</p> <p>13 A. Yes. So that is the difference because it</p> <p>14 doesn't achieve statistical significance; it's very</p> <p>15 close to the line.</p> <p>16 Q. And we just agreed that if you used</p> <p>17 chi-squared it would be significant.</p> <p>18 A. Yes.</p> <p>19 Q. And we also just agreed that one of the</p> <p>20 issues or ramifications of using Fisher's is that</p> <p>21 values that are significant, --</p> <p>22 A. No.</p> <p>23 Q. -- just below the conventional line of</p> <p>24 statistical significance, may be deemed non-</p> <p>25 significant by applying Fisher.</p>	<p>1 exactly .05, so that's not to say that, you know, it's</p> <p>2 not -- it is or isn't significant. It doesn't cross</p> <p>3 the line, which is the criteria for being</p> <p>4 statistically significant.</p> <p>5 Q. Okay. I'm going to try to back up again.</p> <p>6 Your conclusion here on page six of your</p> <p>7 report --</p> <p>8 A. Yeah.</p> <p>9 Q. -- says that one of the reasons the McGovern</p> <p>10 study is not valid is because the p-value is close to</p> <p>11 but not statistically significant; correct?</p> <p>12 A. That's right. The p-value that I'm talking</p> <p>13 about --</p> <p>14 Q. I just want to establish that.</p> <p>15 A. -- is .05 --</p> <p>16 Q. 507.</p> <p>17 A. 507.</p> <p>18 Q. Correct.</p> <p>19 A. That's greater than .05.</p> <p>20 Q. We've also established that when you apply</p> <p>21 chi-squared to the data derived from Albrecht 10 and</p> <p>22 McGovern seven -- 16, that the p-value is 0.048;</p> <p>23 correct?</p> <p>24 A. That's right.</p> <p>25 Q. Just below statistical significance.</p>
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<p>1 A. No, that's not -- that's not what I said.</p> <p>2 They could be close to the line, but that -- that</p> <p>3 doesn't mean they're statistically significant. If</p> <p>4 they're -- if they're not --</p> <p>5 If they don't cross the line, they're not</p> <p>6 significant.</p> <p>7 Q. Okay. So --</p> <p>8 But I'm going to back up because we just</p> <p>9 talked about how one ramification of using Fisher's,</p> <p>10 because there are discrete statistics with fixed</p> <p>11 significance levels, --</p> <p>12 A. Yeah.</p> <p>13 Q. -- that a statistic that is just below the</p> <p>14 line of statistical significance, in the .04 range --</p> <p>15 A. Well if it's below .05 --</p> <p>16 Q. Yes.</p> <p>17 A. -- it's significant, so don't you mean just</p> <p>18 above?</p> <p>19 Q. Well Fisher's would bring it just above;</p> <p>20 correct?</p> <p>21 A. Fisher's would bring it above, --</p> <p>22 Q. Yes.</p> <p>23 A. -- but there --</p> <p>24 The problem is is that you can -- there</p> <p>25 would not be a corresponding table that would give you</p>	<p>1 A. That's right.</p> <p>2 Q. One of Berkson's critiques, whether or not</p> <p>3 you've read the article, you appeared to agree that</p> <p>4 there's an issue with combining discrete statistics</p> <p>5 with fixed significance levels; correct?</p> <p>6 A. I'm --</p> <p>7 Q. You said that was a ramification of using</p> <p>8 Fisher's.</p> <p>9 A. A ramification, --</p> <p>10 Q. Yes.</p> <p>11 A. -- not necessarily a --</p> <p>12 It's a problem with what you're -- with what</p> <p>13 you're trying to do. It is an issue with discrete --</p> <p>14 discrete probability values.</p> <p>15 Q. And an implication of that is that p-values</p> <p>16 that would otherwise be nominally significant, just</p> <p>17 below the conventional limit of .05, would be rendered</p> <p>18 non-significant above .05; correct?</p> <p>19 A. No.</p> <p>20 Q. So you disagree with Joseph Berkson.</p> <p>21 A. I don't think that's --</p> <p>22 I doubt that's what he is saying. I mean</p> <p>23 the premise of what you just said was that the value</p> <p>24 would be significant. Right? Isn't that what you</p> <p>25 said?</p>

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<p>1 Q. I said if you have a -- for example, a 2 p-value of 0.048, which is significant -- 3 A. That is significant, -- 4 Q. Yeah. 5 A. -- but it's less than .05. It's not .05. 6 Q. Well it's significant because it's less than 7 .05; correct? 8 A. Exactly. 9 Q. Okay. So I think we might be missing each 10 other. 11 A. So -- 12 Q. So -- 13 A. So I -- 14 How exactly did you say that statement 15 again, -- 16 Q. Okay. 17 A. -- which is what my problem is? 18 Q. Okay. So when you apply chi-squared -- 19 A. Yeah. 20 Q. -- to the reanalyzed data, we get a p-value 21 of 0.048, correct, which is below -- 22 A. That's -- that's an approximate p-value. 23 Q. Yes. 24 A. That approximate p-value is less than .05. 25 Q. And it's statistically significant because</p>	<p>1 A. I wouldn't say it's better. 2 Q. -- than Fisher? 3 It's equally as good? 4 A. There -- yeah, for large sample size -- 5 Well the results will -- will agree much 6 better as the sample size increases. 7 Q. Is chi-squared better or equally as good as 8 Fisher's when using a well-balanced table? 9 A. "Well-balanced table," what do you mean? 10 Q. I -- I -- I guess two arms that have 11 approximately the same number of data. 12 A. It's -- 13 I don't know if it's better or -- better or 14 worse. How much -- 15 It depends on the balance. It depends -- 16 what's particularly critical is the -- the expected 17 number -- 18 Q. Yes. I'm going to go -- 19 A. -- in the cell, yeah. 20 Q. I'll get here. 21 But you do say in your report that 22 chi-squared works well for comparing proportions when 23 the sample size is large; right? 24 A. That's right. When the -- when the -- when 25 the numbers in all of the cells of the tables are</p>
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<p>1 it's below -- 2 A. It's below. 3 Q. -- 0.05, which is the conventional line for 4 significance. 5 A. That's -- that -- that is one of the -- one 6 of the thoughts used, yes. 7 Q. Yes. When you apply Fisher's, it goes from 8 0.048 to 0.0507; correct? 9 A. That's right. 10 Q. And one of the issues with Fisher's is 11 that it's combining discrete statistics with fixed -- 12 A. Yeah. 13 Q. -- significance levels; right? 14 A. Well it has -- 15 Q. We said that three times. 16 A. -- significant value, yeah. 17 Q. Okay. And the implication of doing that is 18 what you said earlier where a p-value of .04 could 19 then become non-significant by applying Fisher's. 20 A. No. The .04 doesn't -- 21 It's not the .04 is going to this. They're 22 two different -- completely different ways in which 23 these things are computed, so one does not change. 24 Q. Okay. Would you agree that chi-squared is 25 better for larger sample sizes --</p>	<p>1 reasonably large, greater than five is one rule of 2 thumb, -- 3 Q. Yeah. 4 A. -- and then -- then it does pretty -- 5 pretty -- 6 The difference is pretty small. 7 Q. What -- 8 So in terms of just talking about 9 population, -- 10 A. Uh-huh. 11 Q. -- what is a large population in your view? 12 MR. GORDON: Object to the form -- object to 13 the form of the question. 14 Q. So does it depend on what the expected value 15 would be, or could you determine that, okay, 5,000 16 persons is a large population, or, you know, 2,000 is 17 large or 10 -- 18 You know, I'm just trying to understand. 19 Because in your report you say the McGovern population 20 is relatively small, so I'm trying to kind of 21 contrast, well, what's a large population in your 22 view? 23 A. Well it's relatively small because the 24 number of infections in the -- in -- in one of the 25 groups is like, what, three -- three or four depending</p>

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<p>1 on which tabulation it is, so it's less than five.</p> <p>2 Q. So --</p> <p>3 A. So it's that value --</p> <p>4 So I mean 5,000 seems like a large</p> <p>5 population, but if you're looking at an effect that</p> <p>6 occurs one-tenth of one percent of the time --</p> <p>7 Q. Uh-huh.</p> <p>8 A. -- or less than that, then the numbers of</p> <p>9 infected start getting pretty small.</p> <p>10 Q. Got it.</p> <p>11 So do you agree or disagree with this view</p> <p>12 that you can apply Fisher's or chi-squared based on</p> <p>13 one option, which are expected values, and another</p> <p>14 option, which is size of population, just raw</p> <p>15 population?</p> <p>16 A. Just raw population I don't think is as</p> <p>17 critical as -- as values in -- in individual cells.</p> <p>18 That's -- that's -- that's a much more important --</p> <p>19 Q. So --</p> <p>20 A. -- factor than the total size.</p> <p>21 Q. Do you disagree with The Handbook of</p> <p>22 Biostatistics which states that "I recommend you use</p> <p>23 Fisher's exact test when the total sample size is less</p> <p>24 than a thousand?"</p> <p>25 A. I have to read the whole entry in the --</p>	<p>1 A. Okay.</p> <p>2 Q. -- there's a "Summary" section of when to</p> <p>3 use a null hypothesis and how the test works; right?</p> <p>4 A. Yes.</p> <p>5 Q. And under the "When to use it," the very</p> <p>6 last paragraph starts with "Fisher's exact test is</p> <p>7 more accurate" blah, blah, blah; right? The very --</p> <p>8 the last paragraph of the --</p> <p>9 A. Yes.</p> <p>10 Q. -- section there.</p> <p>11 A. Yes.</p> <p>12 Q. The second sentence says, "I recommend you</p> <p>13 use Fisher's exact test when the total sample size is</p> <p>14 less than 1000..."</p> <p>15 A. Okay.</p> <p>16 Q. So is it wrong to conclude that you don't</p> <p>17 need to use Fisher's exact test when the sample size</p> <p>18 is greater than a thousand?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. I'm sorry, could you repeat that?</p> <p>22 Q. So this paragraph is comparing the use of</p> <p>23 Fisher's exact test to chi-squared in the G test.</p> <p>24 A. Yes.</p> <p>25 Q. And this handbook states that you should use</p>
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<p>1 But that doesn't sound quite right. I mean</p> <p>2 I think there would --</p> <p>3 You could have the total sample size be less</p> <p>4 than a thousand and if it's -- you know, if the</p> <p>5 balance among cells is such that the expected values</p> <p>6 of the fields are reasonably large, chi-square would</p> <p>7 do reasonably well.</p> <p>8 (Exhibit 20 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. SACCHET:</p> <p>11 Q. Turning to the last page of the document,</p> <p>12 professor, the citation is "McDonald, J.H. 2014.</p> <p>13 Handbook of Biological Statistics (3rd edition)." Do</p> <p>14 you see that?</p> <p>15 A. Where is this?</p> <p>16 Q. On the last -- on the last page in the most</p> <p>17 full paragraph that's three lines long, the citation</p> <p>18 says this document may be cited as "McDonald, J.H.</p> <p>19 2014. Handbook of Biological Statistics (3rd</p> <p>20 edition)."</p> <p>21 A. Okay.</p> <p>22 Q. Do you see that?</p> <p>23 A. Yeah.</p> <p>24 Q. Okay. And if you go to the first page of</p> <p>25 the document --</p>	<p>1 Fisher's exact test when the sample size is less than</p> <p>2 a thousand; correct?</p> <p>3 A. Yes.</p> <p>4 Q. Do you disagree with the implication of that</p> <p>5 statement, which is you don't need to use Fisher's</p> <p>6 exact test when the sample -- when the sample size is</p> <p>7 greater than a thousand?</p> <p>8 A. I don't think it says that.</p> <p>9 Q. What would it mean when it says it</p> <p>10 recommends to use it when it's less than a thousand?</p> <p>11 That doesn't mean that it's not --</p> <p>12 A. It doesn't -- it doesn't say what to do when</p> <p>13 it's greater than a thousand.</p> <p>14 Q. Okay. But it's your view that you don't</p> <p>15 apply chi-squared if it's greater than a thousand just</p> <p>16 as a raw number?</p> <p>17 A. I don't think it's particularly --</p> <p>18 It doesn't say whether or not -- or not. I</p> <p>19 mean if it's greater than a thousand, there are</p> <p>20 circumstances where I think it's still better to use.</p> <p>21 Q. You've applied chi-squared in populations of</p> <p>22 less than a thousand; haven't you?</p> <p>23 A. I probably have, yeah.</p> <p>24 Q. Is there a reason why in those articles you</p> <p>25 did so but in this report you don't?</p>

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<p>1 A. Well because the numbers were -- in the 2 cells were bigger. 3 Q. Okay. I just want to make sure that that's 4 true. So -- 5 A. Well I don't if I -- 6 I've published a lot of papers, I don't know 7 if I made a mistake in some, but that's generally what 8 I do. If it's -- if it's a small number, I'll do the 9 exact. 10 (Exhibit 21 was marked for 11 identification.) 12 BY MR. SACCHET: 13 Q. Did you author this study, professor? 14 A. I am one of the authors on this study. 15 Q. Okay. 16 A. Fairly far down the list. Okay. 17 Q. The last paragraph in the right-hand column 18 on the first page says that "Of the initial 1,002 19 infants enrolled, 880 were included..." Do you see 20 that? 21 A. Yes. 22 Q. If you turn to internal page 785, -- 23 A. Yes. 24 Q. -- the last paragraph in the left-hand 25 column starts "A major strength..." Do you see that?</p>	<p>1 A. Well we're -- we're talking about two 2 different things. It's small because what's -- in the 3 Hot Dog group there are only three or four infections. 4 Q. So the expected value -- the actual value. 5 A. So if we're looking at -- if you're -- 6 If you -- what you want to do is design a -- 7 an experiment that really addresses the question of 8 whether it reduces the rate of infection, 1400 is -- 9 it's arguable about whether that is large enough a 10 study to do that. 11 Q. So it's unclear whether it's large or small. 12 A. Well I don't recall -- I -- 13 I never saw a power analysis of this study. 14 And if you could show me one, I'd be glad to -- glad 15 to review it. 16 Q. So you never -- 17 A. But -- but the -- the study was not designed 18 in the -- in the typical way that you would design a 19 study if you were seeking NIH funding or something 20 like that where you would be required to generate the 21 sample size. 22 Q. So you haven't -- 23 A. That's what would be required, and that 24 would determine, you know, the -- the -- that would 25 determine -- be more relevant, it seems to me, in</p>
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<p>1 A. Yes. 2 Q. "A major strength of our study is that we 3 collected extensive respiratory symptom data, material 4 asthma allergy histories, and housing characteristic 5 information on a large population at high risk for 6 developing asthma." Do you see that? 7 A. Yes. 8 Q. Was that the large population of eight 9 hundred some infants that you analyzed in this study? 10 A. Yeah. I mean the reference there I -- I 11 think is towards the size of the study in comparison 12 to other studies of children's health and airborne 13 disease. 14 Q. Well you conclude, aside from the Augustine 15 2017 study, that the McGovern study is the only 16 observational data at hand regarding the use of the 17 Bair Hugger or a conductive warming device in deep 18 joint infections; correct? 19 A. Okay. Yeah. 20 Q. And that study had approximately 1400 21 patients; correct? 22 A. Yes. 23 Q. And in that study you're calling it 24 relatively small, but in this study you're calling a 25 population of 800 persons large.</p>	<p>1 terms of the size of the study and whether or not it 2 was big enough to address the particular hypothesis 3 that was being -- that was being proposed in the -- in 4 the proposal. 5 Q. So it's your view that it's a better metric 6 to use expected values than actual values, correct, to 7 determine whether you apply Fisher's instead of 8 chi-squared? 9 A. The -- the -- the typical rule of thumb 10 depends on the expected. In my own bias I've found 11 that sometimes the observed number can be relevant as 12 well. 13 Q. So based on your own bias, you relied on the 14 actual values reported in the study itself as opposed 15 to the expected values that most statisticians rely on 16 to determine whether to apply Fisher or not. 17 A. Yeah. That's probably less commonly used on 18 the observed values, but I prefer to do that because I 19 think in this case, actually, the expected values 20 are -- are greater, I -- I believe, than -- than -- 21 than the nominal five, if that's the rule you're 22 using. 23 Q. The rule of thumb. 24 A. Yeah. If that's the rule you're using, 25 that --</p>

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<p>1 I haven't read this complete article. That</p> <p>2 doesn't seem to be what the person that wrote this</p> <p>3 article for Biological Statistics is using.</p> <p>4 Q. You would agree, though, the general rule of</p> <p>5 thumb with respect to implying -- employing Fisher's</p> <p>6 exact test is whether the expected value is under</p> <p>7 five; correct?</p> <p>8 A. Yeah. I mean there -- there's a difference,</p> <p>9 you understand, between recommending the choice, the</p> <p>10 extra calculation that's involved with doing Fisher</p> <p>11 exact as opposed to the easier calculation of doing</p> <p>12 chi-square; they recommended doing it based on the</p> <p>13 expected value being less than five.</p> <p>14 Q. Uh-huh.</p> <p>15 A. That's not to say that it's wrong to do the</p> <p>16 Fisher's exact test otherwise.</p> <p>17 Q. If you did an expected value calculation</p> <p>18 based on the populations reported in the McGovern</p> <p>19 study, it very well could exceed five for each arm of</p> <p>20 the study; correct?</p> <p>21 A. It could, yeah.</p> <p>22 Q. But you --</p> <p>23 A. We can do it. I --</p> <p>24 Q. I can --</p> <p>25 But you agree that that's possible.</p>	<p>1 Q. You didn't follow the rule of thumb.</p> <p>2 A. I didn't follow the rule of thumb. I</p> <p>3 followed my own rule of thumb.</p> <p>4 Q. And that's contrary to generally accepted</p> <p>5 methods; correct?</p> <p>6 A. Well it's --</p> <p>7 Q. It's a rule of thumb.</p> <p>8 A. It's a rule of thumb that's sometimes</p> <p>9 applied. I mean you apply --</p> <p>10 Who is this, McDonald --</p> <p>11 Q. Yeah.</p> <p>12 A. -- in Exhibit 20?</p> <p>13 Q. Handbook of Biostatistics.</p> <p>14 A. Yeah. And McDonald is using a different</p> <p>15 rule of thumb. He's not --</p> <p>16 Q. Oh --</p> <p>17 A. At least in that first paragraph. I haven't</p> <p>18 read the whole thing.</p> <p>19 Q. He uses the same rule. I'll give you the</p> <p>20 other section of the handbook.</p> <p>21 A. Yeah. Well it's all -- it's all right. I</p> <p>22 mean I know there's -- there's a slight difference in</p> <p>23 how the rule of thumb is sometimes -- sometimes</p> <p>24 applied, but it's a rule of thumb that applies to the</p> <p>25 approximation. What does the approximation -- when</p>
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<p>1 A. Yes.</p> <p>2 Q. And you didn't do it.</p> <p>3 A. I think I did look at it. I think it is a</p> <p>4 little bit greater, the expected value. But based</p> <p>5 on -- as I say, I -- my --</p> <p>6 What I have found very often, that the</p> <p>7 difference can be larger than I like depending on the</p> <p>8 observed number.</p> <p>9 Q. And --</p> <p>10 A. And in fact you see in my --</p> <p>11 Q. Yeah.</p> <p>12 A. -- report there's a difference in</p> <p>13 p-values --</p> <p>14 Q. And --</p> <p>15 A. -- and that's why I did the Fisher. And I</p> <p>16 find a difference.</p> <p>17 Q. Yeah. You -- you use Fisher instead of</p> <p>18 chi-squared; correct?</p> <p>19 A. That's right.</p> <p>20 Q. Even though the expected value is above</p> <p>21 five.</p> <p>22 A. That's right.</p> <p>23 Q. Okay.</p> <p>24 A. As I said, I mean it's not a --</p> <p>25 It's a rule of thumb. It's not a --</p>	<p>1 did the approximation break down, and it particularly</p> <p>2 breaks down if the expectation is small. My</p> <p>3 contention is is that it breaks down also to some</p> <p>4 extent when the observed values are small even though</p> <p>5 the expected values may be large.</p> <p>6 MR. SACCHET: We're going to mark another</p> <p>7 exhibit here.</p> <p>8 (Exhibit 22 was marked for</p> <p>9 identification.)</p> <p>10 A. The discreteness, for example, that we were</p> <p>11 just talking about would also come into play to some</p> <p>12 extent on chi-square, because I mean whenever you're</p> <p>13 dealing with integers, the -- the chi-square</p> <p>14 statistics that you -- that you get at the end is only</p> <p>15 going to take discrete values, it's not going to take</p> <p>16 a complete -- a continuum of values. So the</p> <p>17 particular criticism that -- that comes into play with</p> <p>18 Fisher's also, I would say, comes into effect to some</p> <p>19 extent on chi-square.</p> <p>20 Q. This --</p> <p>21 If you turn to the last page of this</p> <p>22 document, professor, is also part of McDonald's 2014</p> <p>23 Handbook on Biological Statistics; correct?</p> <p>24 A. Apparently.</p> <p>25 Q. Last page of the document. Do you see that</p>

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<p>1 citation in the third kind of --</p> <p>2 A. Yeah, appears to be.</p> <p>3 Q. Yeah. And if you turn to page four of the</p> <p>4 document under "Similar tests" --</p> <p>5 Do you see that heading?</p> <p>6 A. Yes.</p> <p>7 Q. In the third paragraph, the very first line</p> <p>8 says, "The usual rule of thumb is that you should use</p> <p>9 the exact test when the smallest expected value is</p> <p>10 less than 5...;" correct?</p> <p>11 A. Where did you see this?</p> <p>12 Q. Are -- are you on page four? On the very</p> <p>13 top of the document there's pages X through seven.</p> <p>14 Are you on page four?</p> <p>15 A. Yeah. Which paragraph were you on?</p> <p>16 Q. Was I looking at the wrong document?</p> <p>17 There's a heading called "Similar tests."</p> <p>18 A. That's right.</p> <p>19 Q. Okay. And then in the -- I guess it's the</p> <p>20 fourth paragraph because the first line just a sole</p> <p>21 line, the paragraph begins, "The usual rule of</p> <p>22 thumb" --</p> <p>23 A. Oh, okay.</p> <p>24 Q. -- "is that you should use the exact test</p> <p>25 when the smallest expected value is less than 5..."</p>	<p>1 Q. .048. Yeah.</p> <p>2 A. Well that's a difference --</p> <p>3 Q. I don't think mine's right.</p> <p>4 A. -- of .0027.</p> <p>5 Q. 0027.</p> <p>6 A. Yeah.</p> <p>7 Q. And that is, in percentage value, .27</p> <p>8 percent; correct?</p> <p>9 A. Correct.</p> <p>10 Q. And as a raw figure it's -- forgive my</p> <p>11 mathematical ignorance -- two-thousandths of a decimal</p> <p>12 point?</p> <p>13 A. Two --</p> <p>14 Well it rounds up to, I think, three. But</p> <p>15 anyway, yeah.</p> <p>16 Q. Okay. Three-thousandths of a decimal point?</p> <p>17 A. Right.</p> <p>18 Q. And that's the basis by which you say that</p> <p>19 the McGovern data goes from non-significance to</p> <p>20 significance -- or significance to non-significance;</p> <p>21 correct?</p> <p>22 A. No. I mean the definition of -- of</p> <p>23 significance, is it above or below the line?</p> <p>24 Q. That's the conven --</p> <p>25 A. Critically thinking, that's the -- that's</p>
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<p>1 A. That's right. Yeah, I -- I thought you were</p> <p>2 referring to the third paragraph.</p> <p>3 Okay. Yes.</p> <p>4 Q. So that that corroborates the fact that in</p> <p>5 this handbook the rule of thumb is that the expected</p> <p>6 value should be less than five to apply Fisher's.</p> <p>7 A. Yeah, which is what I -- which is what I</p> <p>8 said, you know, --</p> <p>9 Q. Okay.</p> <p>10 A. -- a few minutes ago.</p> <p>11 Q. Okay. As to the p-value that you calculated</p> <p>12 using Fisher's instead of chi-squared, on the data</p> <p>13 derived from Albrecht 10 and McGovern 16 the p-value,</p> <p>14 as we stated, is 0.0507; correct?</p> <p>15 A. That's the value I got, yes.</p> <p>16 Q. And the difference between that p-value and</p> <p>17 the p-value when you use chi-squared on the reanalyzed</p> <p>18 data of 0.048 is a matter of a thousandth of a decimal</p> <p>19 place; correct?</p> <p>20 A. Well it's point -- it's twen --</p> <p>21 It's a difference of .2 -- 027; right?</p> <p>22 Q. I've got a difference of .0009.</p> <p>23 A. I thought we were comparing --</p> <p>24 Q. Let's see. The difference between .0507 --</p> <p>25 A. And .048.</p>	<p>1 the definition of it.</p> <p>2 Q. It's a conventional line; correct?</p> <p>3 A. It's the line that's often used. It's</p> <p>4 obviously arbitrary, but it's the one that is very</p> <p>5 often used.</p> <p>6 Q. You agree that it's arbitrary.</p> <p>7 A. Oh, yeah.</p> <p>8 Q. And do you agree with The American</p> <p>9 Statistical Association's recent statement that the</p> <p>10 confidence levels of five percent and 10 percent are,</p> <p>11 quote, "at best useful conventions?"</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question.</p> <p>14 A. I mean they're -- they're conventions that</p> <p>15 are often used, yeah.</p> <p>16 Q. Do you agree with the statement that they</p> <p>17 are at best useful conventions?</p> <p>18 MR. GORDON: Same objection.</p> <p>19 A. That sounds -- I --</p> <p>20 I think I would agree with that.</p> <p>21 Q. Are you aware that certain peer-reviewed</p> <p>22 journals have recently decided to ban the use of</p> <p>23 p-values?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question, lack of foundation.</p>

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<p style="text-align: right;">Page 213</p> <p>1 A. I'm aware that some journals some time 2 ago -- I'm not sure, I thought they had retracted on 3 that somewhat more recently, but there was a -- there 4 was a period of time where they went through -- some 5 journals went through that -- the thing about -- 6 about -- about the p-values. 7 Q. Do you know Ron Wasserstein, who I think is 8 the president of the ASA? 9 A. I don't know him, -- 10 Q. Okay. 11 A. -- no. 12 Q. Would you agree with his statement that the 13 p-value is not intended to be a substitute for 14 scientific reasoning? 15 MR. GORDON: Object to the form of the 16 question and lack of foundation. 17 A. You know, I'm -- I'm not sure what the whole 18 statement was that he is -- that he is talking about. 19 I mean certainly on the surface that -- 20 It's not -- it's not the sole basis for 21 scientific reasoning, is that what you're saying? I 22 mean -- 23 Q. His quote is the p-value is never intended 24 to be a substitute for scientific reasoning, end 25 quote.</p>	<p style="text-align: right;">Page 215</p> <p>1 Q. My question is just about this p-value which 2 you use on page six of your report where you say, "The 3 reasons why McGovern et al conclusions are not valid 4 is because the p-value is close but not statistically 5 significant." That's one of your conclusions; is that 6 not correct? 7 A. Well the -- my con -- yes, my -- 8 Well, what I'm saying is the evidence is not 9 strong. Whether you say the p-value is .0507 -- 10 Q. Okay. 11 A. -- or .048, those are not wildly small 12 p-values to say that there is extremely strong 13 evidence here of an association. 14 Q. But you would agree that the fact that it's 15 just over statistical significance does not mean that 16 the results are invalid. 17 A. The conclusions -- 18 My conclusions are not terribly different 19 from either one of those p-values. 20 Q. Okay. So whether -- 21 A. They're -- they're -- 22 Q. -- it's marginally significant or just over 23 statistical significance does not matter. 24 A. They're -- they're all -- both on the 25 border.</p>
<p style="text-align: right;">Page 214</p> <p>1 A. Okay. 2 Q. Do you agree with that statement? 3 A. Yeah, uh-huh. 4 Q. And do you also agree with the statement 5 that p-values -- a p-value of less than .05 is not a 6 line that separates real results from false ones? 7 A. Well certainly, yeah. 8 Q. Okay. So if those -- 9 Well I'll ask you one more question. Do you 10 agree that practices that reduce data analysis or 11 scientific inference to mechanical bright-line rules, 12 such as the p-value of being less than .05 for 13 justifying scientific claims or conclusions, can lead 14 to erroneous beliefs and poor decision-making? 15 A. Yes. 16 Q. One of your conclusions in this report is 17 that the McGovern data is invalid because the p-value 18 is .0507; correct? 19 A. Well I think that's a -- 20 You're mixing -- you're mixing different -- 21 different issues here. McGovern, as I understand the 22 way it's being used here, is to -- is not as a -- it's 23 used to try to say that there is strong scientific 24 evidence that infection rates for Bair Hugger are 25 higher than the Hot Dog warmer.</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. Okay. 2 A. I mean what I'm doing, if -- and what I -- 3 Part of what I'm commenting here and part of 4 what I would disagree with is a comparison with what 5 Samet is saying. 6 Q. Okay. We'll get to that. 7 A. Samet is saying that the evidence is very 8 strong. 9 Q. Okay. 10 A. Okay? And what I'm saying is that it's not 11 that strong, it's right on the cusp. 12 Q. Are you aware that under the law, the 13 Supreme Court of the United States of America has 14 stated that statistically significant p-values are not 15 necessary to determine causation? 16 MR. GORDON: Object to the form of the 17 question and lack of foundation. 18 A. I -- I'm not familiar with -- with what the 19 Supreme Court said or exactly what they were dealing 20 with. 21 Q. So your report does not account for the 22 legal standard that applies to determinations of 23 causation as a matter of law. 24 MR. GORDON: Object to the form of the 25 question, lack of foundation.</p>

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<p>1 A. Is that --</p> <p>2 Is the Supreme Court talking about a matter</p> <p>3 of -- matter of law, or you were -- you were stating</p> <p>4 it as -- as scientific -- as a scientific -- statement</p> <p>5 of scientific fact?</p> <p>6 Q. Quote, "A lack of statistically significant</p> <p>7 data does not mean that a medical expert has no</p> <p>8 reliable basis for inferring a causal link between a</p> <p>9 product and an adverse event," end quote.</p> <p>10 A. The lack of -- I -- I --</p> <p>11 I don't know.</p> <p>12 MR. GORDON: I'll object to the form of the</p> <p>13 question.</p> <p>14 A. Yeah. I don't really understand what --</p> <p>15 what they're -- what they're getting at. I would have</p> <p>16 to --</p> <p>17 Q. Would it help to see the statement?</p> <p>18 A. I'd have to review the statement. I mean</p> <p>19 how --</p> <p>20 What is it, a whole report?</p> <p>21 Q. It's a case, and we don't have time for you</p> <p>22 to read the whole case, but --</p> <p>23 A. I mean that's --</p> <p>24 I'd have to figure out what the case is</p> <p>25 talking about. It -- it's --</p>	<p>1 Q. And you conclude that one of the issues with</p> <p>2 that confidence interval is it's essentially 10 points</p> <p>3 and therefore there's -- there could be unreliability</p> <p>4 to the data; correct?</p> <p>5 A. Well the estimate of the -- of the odds</p> <p>6 ratio is -- is not precise at all. I mean it's a</p> <p>7 ten-fold difference, ten-fold range.</p> <p>8 Q. So I was confused because when I read your</p> <p>9 report and I saw your real analysis of the Jensen</p> <p>10 data --</p> <p>11 Which you did applying Albrecht Exhibit 10;</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. -- the confidence interval of your</p> <p>15 calculation is 25 points wide.</p> <p>16 A. I forget what the range was. It was pretty</p> <p>17 wide.</p> <p>18 Where was it?</p> <p>19 Q. It's on page five.</p> <p>20 A. Page five. So you're referring to the 1.37</p> <p>21 to 25.49.</p> <p>22 Q. Yeah.</p> <p>23 A. Yeah. Yeah. It's not a very good estimate.</p> <p>24 Q. It's double the size of the confidence</p> <p>25 interval that you critique with respect to the</p>
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<p>1 I'm not a lawyer, obviously, and so I'm --</p> <p>2 I'm not sure what distinctions that they're -- that</p> <p>3 they're making. Their language is sometimes a little</p> <p>4 different.</p> <p>5 MR. SACCHET: Okay. Let's take a break.</p> <p>6 THE REPORTER: Off the record, please.</p> <p>7 (Recess taken.)</p> <p>8 BY MR. SACCHET:</p> <p>9 Q. Professor Holford, in your report you also</p> <p>10 note that applying Fisher's exact test on the data</p> <p>11 derived from Albrecht Exhibit 10 and McGovern Exhibit</p> <p>12 16 yields a confidence interval of .97 to 10.82;</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. And essentially that .97 is just .03 away</p> <p>16 from the null value of one; correct?</p> <p>17 A. That's right.</p> <p>18 Q. So it's subject to this same debate about</p> <p>19 just over/just under.</p> <p>20 A. It's just -- it's just under the critical</p> <p>21 value.</p> <p>22 Q. Yes.</p> <p>23 A. I mean it corresponds --</p> <p>24 It's a little less because the p-value is a</p> <p>25 little high.</p>	<p>1 McGovern study; correct?</p> <p>2 A. That's right. It's statistically</p> <p>3 significant, but the -- but the -- but it's not a good</p> <p>4 estimate of what the risk is.</p> <p>5 Q. So it has double the variance as the</p> <p>6 confidence interval in the McGovern study.</p> <p>7 A. Well it's -- it seems to be double the --</p> <p>8 the range, the -- the -- the length of the -- of the</p> <p>9 confidence interval.</p> <p>10 Q. But you rely on this calculation with</p> <p>11 respect to arguing whether or not the</p> <p>12 thromboprophylaxis that was used in the McGovern study</p> <p>13 is in fact a confounding factor; correct?</p> <p>14 A. Well I'm --</p> <p>15 I was looking at the p-value. The p-value</p> <p>16 that I get associated with that is .006 --</p> <p>17 Q. Uh-huh.</p> <p>18 A. -- 4, so it's quite a small p-value. The</p> <p>19 estimate of what that effect is is quite imprecise</p> <p>20 because of -- you know, because of the range that we</p> <p>21 were just talking about.</p> <p>22 Q. It's more imprecise than the McGovern</p> <p>23 study's confidence interval that you critique.</p> <p>24 A. Well it's more imprecise in --</p> <p>25 In general what happens with the -- with</p>

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<p style="text-align: right;">Page 221</p> <p>1 the -- with the confidence interval is it kind of 2 depends on the logarithm, so it's more on the log 3 scale, so that's part of what happens. I mean this 4 odds ratio is 4.77, so it's quite a bit bigger than 5 the odds ratios we were finding associated with Bair 6 Hugger use. So that's -- that's of course just a 7 point estimate, and so we're talking about a higher 8 range, so the range is going to be -- going to tend to 9 be somewhat wider because -- because we're up there. 10 And of course the -- the total sample size, total 11 number of individuals involved is -- is quite a bit 12 smaller than -- than -- because it -- it's just 13 based -- 14 It comes out to be a subset of the -- of the 15 Bair Hugger study because it's only the Bair Hugger 16 period, so it's reduced in that way, and then the 17 other thing is that it's not the entire period, it's 18 just part of it, so we -- you're splitting that data 19 set up. And so your total sample size has gone down, 20 and that increases the -- that decreases the sample 21 size and in general makes the estimates less precise. 22 Q. But there's no doubt that the confidence 23 interval in this Jensen reanalysis, which is in your 24 report on page five, is double the width of the 25 McGovern confidence interval; correct?</p>	<p style="text-align: right;">Page 223</p> <p>1 A. Well the accuracy depends on -- on the -- on 2 the -- 3 Q. Cross product. 4 A. Well the point estimate is the cross 5 product. The -- the confidence interval depends on 6 this Fisher-like distribution. It's not -- 7 It's an exact kind of calculation that -- 8 that -- that's involved, but it's kind of a lengthy 9 calculation that roughly depends on the standard 10 error. 11 Q. So I might need to back up because I don't 12 know if I'm fully understanding what you're saying. 13 But the odds ratio reported in the McGovern study was 14 3.8; correct? 15 A. Yes. 16 Q. And then in your report on page two you say 17 the odds ratio for this comparison is 2.76, and 18 what -- 19 A. That's in the tabulation I used, yes. 20 Q. -- what data are you using to derive that 21 odds ratio? 22 A. The -- 23 MR. GORDON: Arithmetically, or the 24 underlying data? 25 MR. SACCHET: Arithmetically.</p>
<p style="text-align: right;">Page 222</p> <p>1 A. That seems to be what it is, yes. 2 Q. That is what it is. 3 A. Okay. Yeah. 4 Q. Your report also states that when applying 5 Albrecht Exhibit 10 and McGovern Exhibit 16, that the 6 p-value -- or that the odds ratio is 2.76 when using 7 Fisher's exact; correct? 8 A. Well that -- that -- yeah. And that -- 9 that's not -- 10 The -- the test, the Fisher's exact, has to 11 do with the p-value, not the -- not the estimate of 12 what the odds ratio is. 13 Q. So on page two of your report when you say 14 the odds ratio for this comparison is 2.76, where did 15 you get that from? 16 A. That's just a cross-product ratio for that 17 table. 18 Q. And is that -- okay. 19 So the 2.76 derives from Albrecht Exhibit 10 20 and McGovern Exhibit 16. 21 A. That's right. It's a tabulation of those 22 data. I mean it's -- 23 Yeah. 24 Q. And it's only accurate insofar as those 25 exhibits are accurate; correct?</p>	<p style="text-align: right;">Page 224</p> <p>1 A. Well it's the -- it's the -- two point -- 2 Where is that? Oh, here we are. Okay. 3 Yeah. That's based on this -- this table that is the 4 four out of 372 and 31 out of 1065. 5 Q. And where did you get that data? 6 A. That's from -- from -- 7 Was it Albrecht 10? 8 Q. Okay. You would agree that that odds ratio 9 is still above 2.0; correct? 10 A. Yes. 11 Q. Would you agree that an odds ratio of 2.0 is 12 often referred to as a doubling of the risk? 13 A. It -- it is, yeah. 14 Q. And -- and that means you're 50 percent more 15 likely to experience the outcome after exposure to the 16 variable than the count as actual? 17 MR. GORDON: Object to the form of the 18 question. 19 A. Well if -- what it would imply, if -- if -- 20 if the odds ratio was -- if the -- 21 The odds ratio is actually a ratio of odds. 22 The statement that you made as -- is re -- is 23 related -- you state it as a ratio of -- of risks, 24 which would typically mean a ratio of the -- of the 25 incidence rates.</p>

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<p style="text-align: right;">Page 225</p> <p>1 Q. Okay.</p> <p>2 A. So when the incidence rates are small, those</p> <p>3 two are very similar, okay, and so they're roughly</p> <p>4 used in that way. So an odds ratio of two, it's --</p> <p>5 strictly speaking it's twice the odds of getting an</p> <p>6 infection, although it's going to be very close as --</p> <p>7 to -- to twice the incidence.</p> <p>8 Q. Okay.</p> <p>9 A. So if -- well if -- if you're saying that</p> <p>10 the -- the Hot Dog is the norm and the odds ratio is</p> <p>11 two, that would say that the Bair Hugger has twice the</p> <p>12 risk.</p> <p>13 Q. Okay.</p> <p>14 A. That's how -- how you would roughly</p> <p>15 interpret that statement.</p> <p>16 Q. Okay.</p> <p>17 A. Depending on whether or not -- whether that</p> <p>18 statement is correct we might disagree on, but --</p> <p>19 Q. So if the incidence of disease in an exposed</p> <p>20 group is more than twice the incidence in the</p> <p>21 unexposed group, the probability that exposure to the</p> <p>22 agent caused a similarly situated individual is also</p> <p>23 greater than 50 percent; correct?</p> <p>24 A. If -- if that estimate is -- is accurate,</p> <p>25 that's roughly what it would -- what it would be --</p>	<p style="text-align: right;">Page 227</p> <p>1 A. That's right.</p> <p>2 Q. They are two different time periods;</p> <p>3 correct?</p> <p>4 A. That's correct.</p> <p>5 Q. That's an apples-to-orange comparison; isn't</p> <p>6 it?</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question.</p> <p>9 Q. Let me put it this way: It's not externally</p> <p>10 generalizable.</p> <p>11 A. It's not --</p> <p>12 What do you mean?</p> <p>13 Q. It's not externally valid. I mean if -- if</p> <p>14 you're looking at a date range of 2010 to 2015, you</p> <p>15 don't know for sure whether that --</p> <p>16 A. Yeah.</p> <p>17 Q. -- infection rate should apply to prior</p> <p>18 years; do you?</p> <p>19 A. Well if -- if things are reasonably --</p> <p>20 I mean the -- the assumption there is that</p> <p>21 there's not a huge temporal trend going on in</p> <p>22 infection rates in the U.K., and so my -- my</p> <p>23 assumption is -- I -- I didn't have --</p> <p>24 Ideally, I would have had the data for the</p> <p>25 same years. I didn't.</p>
<p style="text-align: right;">Page 226</p> <p>1 what it -- what it would mean.</p> <p>2 Q. Thank you.</p> <p>3 Okay. I'd like to talk a little bit about</p> <p>4 the other section of your report which deals with the</p> <p>5 time trend infection rates at Wansbeck, and I guess</p> <p>6 really the -- the big header is "Infection rate</p> <p>7 comparison among hospitals" starting on page three, at</p> <p>8 the bottom of page three, and then continuing into</p> <p>9 four and five.</p> <p>10 So to be clear, in your report you note that</p> <p>11 there is a .6 percent infection rate among NHS trust</p> <p>12 in 2010 to 2015; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And when you cite a 2.9 percent infection</p> <p>15 rate at the top of page four, that is based also on</p> <p>16 the Albrecht Exhibit 10 and McGovern Exhibit 16 data;</p> <p>17 correct?</p> <p>18 A. That's right.</p> <p>19 Q. And to be clear, that infection rate as it</p> <p>20 relates to Bair Hugger patients was during the 2008</p> <p>21 and 2009 time period; correct?</p> <p>22 A. That's correct.</p> <p>23 Q. So you are comparing an infection rate of</p> <p>24 Bair Hugger patients in 2008 and 2009 to an infection</p> <p>25 rate from 2010 to 2015.</p>	<p style="text-align: right;">Page 228</p> <p>1 Q. Okay.</p> <p>2 A. And so I used the best data that I could get</p> <p>3 ahoid of to -- to see what the experience was at other</p> <p>4 hospitals using Bair Hugger at this time to get a</p> <p>5 comparison of how Wansbeck fit -- fit in with the --</p> <p>6 with the experience at other hospitals.</p> <p>7 Q. Did you try to get data from 2008 to 2009?</p> <p>8 A. I didn't have -- I didn't have a -- didn't</p> <p>9 come across a good way of doing that.</p> <p>10 Q. Okay. But you recognize that it's two</p> <p>11 different time periods.</p> <p>12 A. Yes, I do. Uh-huh.</p> <p>13 Q. Are you aware of infection rates in the</p> <p>14 United States as opposed to infection rates reported</p> <p>15 by the NHS in the U.K.?</p> <p>16 A. No. I don't know what the rates are in the</p> <p>17 U.S.</p> <p>18 Q. So you do not know whether the rates of</p> <p>19 infection as reported in the McGovern study are</p> <p>20 comparable to rates in the United States.</p> <p>21 A. I don't have a direct es -- estimate of</p> <p>22 rates in the United States. My assumption is that</p> <p>23 they're not too different, but --</p> <p>24 Q. But --</p> <p>25 A. -- I don't know. I don't have the data.</p>

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<p>1 Q. -- with respect to your analysis as to</p> <p>2 whether the time trend data of infections as reported</p> <p>3 in McGovern is out of control, as you say, that is</p> <p>4 only as compared to hospitals in the U.K. from 2010 to</p> <p>5 2015.</p> <p>6 A. In terms of the magnitude of the effect,</p> <p>7 that's -- that was one of the pieces of evidence that</p> <p>8 I was -- that I was looking at.</p> <p>9 Q. But it's only specific to hospitals in the</p> <p>10 U.K.</p> <p>11 A. That's right. I was using data in the U.K.</p> <p>12 Q. Okay.</p> <p>13 (Exhibit 23 was marked for</p> <p>14 identification.)</p> <p>15 BY MR. SACCHET:</p> <p>16 Q. Professor Holford, is this a graph bearing</p> <p>17 the title "Joint infection rate in BH unit sales by</p> <p>18 year?"</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And do you know what ICD codes are?</p> <p>21 A. Yes. Those are disease codes for -- for</p> <p>22 different diseases, yes, that are standardized.</p> <p>23 Q. They relate to disease in the United States.</p> <p>24 A. Are they only -- I don't -- I'm not sure</p> <p>25 what -- what they use --</p>	<p>1 graph is titled "Joint Infection Rates" and then it</p> <p>2 lists an ICD code; correct?</p> <p>3 A. Right.</p> <p>4 Q. Or codes. Correct?</p> <p>5 A. Right.</p> <p>6 Q. And those percentages range from zero to</p> <p>7 six, at least as depicted on the graph, correct, on</p> <p>8 the Y axis on the right-hand side?</p> <p>9 A. That's right.</p> <p>10 Q. Okay. And whichever --</p> <p>11 Well let's look at 2008, and that's when the</p> <p>12 Bair Hugger study period started; correct?</p> <p>13 A. 2008. Okay.</p> <p>14 Q. And the lower orange line, the dot there is</p> <p>15 approximately four percent; correct?</p> <p>16 A. Four percent.</p> <p>17 MR. GORDON: Again, lack of foundation.</p> <p>18 A. Seems to be.</p> <p>19 Q. And the dot above that is between four and</p> <p>20 five.</p> <p>21 A. Somewhere --</p> <p>22 Something, yeah.</p> <p>23 Q. Okay.</p> <p>24 A. What are the two lines? I don't</p> <p>25 understand, --</p>
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<p>1 I don't know what they use in the U.K. This</p> <p>2 is U.S. data, is it?</p> <p>3 Q. I'll represent to you that it is.</p> <p>4 A. Okay.</p> <p>5 Q. And there are three colored lines; correct?</p> <p>6 A. That's correct.</p> <p>7 Q. And to be clear, the title is "Joint</p> <p>8 infection rate...;" correct?</p> <p>9 A. "Joint" --</p> <p>10 Yes.</p> <p>11 Q. Of the graph.</p> <p>12 A. "Joint infection rate..."</p> <p>13 Q. Not like surgical-site infection or other</p> <p>14 type of infection, this is specific to joint</p> <p>15 infection; correct?</p> <p>16 A. That's right.</p> <p>17 Q. Okay. And the two orange-colored lines</p> <p>18 relate to infection rates; correct?</p> <p>19 MR. GORDON: Objection, lack of foundation.</p> <p>20 A. I don't know. I --</p> <p>21 Q. Do you see the legend?</p> <p>22 A. Oh, I see.</p> <p>23 Q. Do you see the legend at the bottom?</p> <p>24 A. Yeah. Okay.</p> <p>25 Q. And then the Y axis on the right side of the</p>	<p>1 Q. So there's an infection rate --</p> <p>2 A. -- it's hard to read.</p> <p>3 Q. And I'm not going to focus on which line,</p> <p>4 you know, we need to focus on, I just want to</p> <p>5 establish that both lines depict infection rates --</p> <p>6 A. Okay.</p> <p>7 Q. -- equal to or greater than four but less</p> <p>8 than five in 2008; correct?</p> <p>9 A. Yeah.</p> <p>10 Q. Okay. And then in 2010 the dots appear to</p> <p>11 be the same, somewhere between four and five; correct?</p> <p>12 A. Right.</p> <p>13 Q. And in fact in 2011 they went up to</p> <p>14 approximately 4.5 and five; correct?</p> <p>15 A. Appears to, yeah.</p> <p>16 Q. Yeah. So if we can find the graph to the</p> <p>17 Bair Hugger study period, which is 2008 to 2010, based</p> <p>18 on this graph the infection rate is four percent or</p> <p>19 perhaps 4.5 percent; correct?</p> <p>20 A. Infection --</p> <p>21 MR. GORDON: Objection, lack of foundation.</p> <p>22 A. So I -- I mean what -- what do these -- what</p> <p>23 do the ICD codes --</p> <p>24 Q. ICD codes --</p> <p>25 I can't testify, but ICD codes, as you</p>

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<p style="text-align: right;">Page 233</p> <p>1 stated earlier, --</p> <p>2 A. Yeah.</p> <p>3 Q. -- relate to particular outcomes of disease.</p> <p>4 A. No. But what is ICD-9 -- 996.66?</p> <p>5 Q. I don't know the answer to that question,</p> <p>6 but I can tell you that 3M's corporate representative,</p> <p>7 Mr. Van Duren, testified that this graph depicts the</p> <p>8 rate of Bair Hugger segment penetration with the rate</p> <p>9 of joint infections.</p> <p>10 A. Okay. So these are some sort of --</p> <p>11 I'm having a hard time understanding what</p> <p>12 you're trying to show here --</p> <p>13 Q. I'm -- I'm --</p> <p>14 A. -- because, I mean, we've got two</p> <p>15 different -- two different lines of the infection</p> <p>16 rates --</p> <p>17 Q. So my question is --</p> <p>18 A. -- and when -- when I --</p> <p>19 I don't know what these two different lines</p> <p>20 are.</p> <p>21 Q. Okay. My question is simple.</p> <p>22 A. Okay.</p> <p>23 Q. Whichever line you choose, the infection</p> <p>24 rate, according to this graph, in 2008 and 2010 was</p> <p>25 4.0 or 4.5; --</p>	<p style="text-align: right;">Page 235</p> <p>1 ICD codes relate to joint infection as the graph is</p> <p>2 entitled, --</p> <p>3 A. Okay.</p> <p>4 Q. -- the infection rate of four percent is</p> <p>5 higher than the infection rate reported by McGovern et</p> <p>6 al.</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question, lack of foundation, assumes facts not in</p> <p>9 evidence, incomplete hypothetical.</p> <p>10 A. Well I mean what I don't understand about</p> <p>11 your question is that you -- there's not a -- there's</p> <p>12 no evidence of how this definition of joint infection</p> <p>13 compares to what McGovern was looking at. What's the</p> <p>14 denominator? What are -- what are -- exactly are --</p> <p>15 I mean are these specific knee and hip</p> <p>16 surgeries? I don't -- I don't know.</p> <p>17 Q. Well just is --</p> <p>18 A. It doesn't say.</p> <p>19 Q. Okay. Assuming that it involves a different</p> <p>20 category of infections, just for the sake of argument,</p> <p>21 that's also a different group than looking at patients</p> <p>22 from 2010 to 2010, isn't it, when the McGovern study</p> <p>23 was about Bair Hugger patients from 2008 to 2009,</p> <p>24 2010?</p> <p>25 A. Well, but I think -- I mean it does say --</p>
<p style="text-align: right;">Page 234</p> <p>1 A. Okay.</p> <p>2 Q. -- is that correct?</p> <p>3 MR. GORDON: Objection, lack of foundation,</p> <p>4 assumes facts not in evidence, incomplete</p> <p>5 hypothetical.</p> <p>6 Q. According to this graph.</p> <p>7 A. Those numbers that are shown, I don't -- and</p> <p>8 as I say, I don't know what they are, you haven't told</p> <p>9 me what they are, there's not a legend here that</p> <p>10 exactly indicates what they are --</p> <p>11 Q. The graph is called "Joint infection</p> <p>12 rate...;" right?</p> <p>13 A. That's what it -- that's what it's called.</p> <p>14 Q. Okay.</p> <p>15 A. But I mean if you look up the ICD code,</p> <p>16 they're very specific on what -- what -- what they</p> <p>17 mean. They're -- they're pretty speci -- specific,</p> <p>18 and I just -- I don't know how those values -- how</p> <p>19 those codes compare with --</p> <p>20 I -- I mean I don't know where you're going</p> <p>21 with this, if you want to compare these values to the</p> <p>22 experience in -- in the U.K. or what -- what exactly</p> <p>23 you're -- you're looking at.</p> <p>24 Q. I'll -- I'll just cut to it. Based on this</p> <p>25 graph -- and I'll make the assumption that these I --</p>	<p style="text-align: right;">Page 236</p> <p>1 If you look at this graph, I mean those</p> <p>2 orange lines are not changing very much between 1996</p> <p>3 and 2012. Okay? They're pretty flat. And so my</p> <p>4 comparison of -- of these two periods for the U.K.,</p> <p>5 one of which was, what, --</p> <p>6 Q. Two thousand --</p> <p>7 A. -- two thousand --</p> <p>8 Let's see. Bair Hugger is '8 to '9 and the</p> <p>9 plot in this case, Fig. 1, has to do with '10 to '15.</p> <p>10 Okay. So based on this, it doesn't seem to be -- look</p> <p>11 to -- to my eyes to be a whole lot different</p> <p>12 between -- before 2010 and between '10 and '15.</p> <p>13 Q. Okay.</p> <p>14 A. Would you agree?</p> <p>15 Q. You assume, in calculating the deep joint</p> <p>16 infection rate in the NHS, that there was complete</p> <p>17 reporting practices among hospitals; correct?</p> <p>18 A. Yeah, that's my assumption. Yeah.</p> <p>19 Q. And if there were not complete reporting</p> <p>20 practices, those averages would be subject, again, to</p> <p>21 a data artifact; correct?</p> <p>22 A. Yes.</p> <p>23 Q. You said that you reviewed Dr. Reed's</p> <p>24 testimony; correct?</p> <p>25 A. Yes.</p>

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<p style="text-align: right;">Page 237</p> <p>1 Q. And did you see where Dr. Reed said that</p> <p>2 "Not every trust puts in the data as we have</p> <p>3 established and the infection rates that they quote</p> <p>4 were very low. And in fact government advisors on</p> <p>5 infection have publicly written to say that their</p> <p>6 quotes -- they quote very low infection rates,</p> <p>7 unrealistically low, because the surveillance system</p> <p>8 is poor in many trusts."</p> <p>9 A. Okay. I mean it -- it may well be.</p> <p>10 Q. So if it may well be, the .6 percent rate</p> <p>11 that you report in your study may also well be subject</p> <p>12 to data artifact.</p> <p>13 A. The accuracy of -- of -- of that value</p> <p>14 depends on the accuracy of the data that were reported</p> <p>15 in the file that I looked at.</p> <p>16 Q. And in your report you relied on Mr.</p> <p>17 Reed's -- Dr. Reed's testimony regarding other subject</p> <p>18 matter; correct?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. Yes, some of the other subject matter. I</p> <p>22 mean I --</p> <p>23 Q. You have no reason to doubt Mr. Reed's</p> <p>24 testimony regarding the --</p> <p>25 A. I --</p>	<p style="text-align: right;">Page 239</p> <p>1 Bair Hugger do not use other warming devices; correct?</p> <p>2 A. That was --</p> <p>3 I mean the assumption was that the primary</p> <p>4 warmers that they were using in these hospitals was in</p> <p>5 fact the Bair Hugger.</p> <p>6 Q. In your report you state that 3M provided</p> <p>7 you with documents that delineated whether or not a</p> <p>8 hospital uses the Bair Hugger; correct?</p> <p>9 A. I was provided with hospitals that were</p> <p>10 using Bair Hugger and that's what I used. I don't --</p> <p>11 didn't go into the detail of the -- of what was used</p> <p>12 in these hospitals.</p> <p>13 Q. So you didn't know based on those documents</p> <p>14 because they didn't specify whether or not those</p> <p>15 hospitals also used other devices.</p> <p>16 A. The documents did not specify. The</p> <p>17 documents --</p> <p>18 The indication that I had was that they</p> <p>19 used -- were using Bair Hugger.</p> <p>20 Q. Are you aware that some hospitals in the NHS</p> <p>21 used both Bair Huggers and conductive warmers?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, lack of foundation, assumes facts not in</p> <p>24 evidence.</p> <p>25 A. I have not seen any data that -- that breaks</p>
<p style="text-align: right;">Page 238</p> <p>1 Q. -- incomplete --</p> <p>2 A. Yeah. I really don't --</p> <p>3 I mean I have -- I have no reason to</p> <p>4 question pro or con the -- the quality of the -- of</p> <p>5 the U.K. data, the -- the NHS data.</p> <p>6 Q. Do you rely on Dr. Reed's testimony only</p> <p>7 when it supports your conclusions?</p> <p>8 A. No. It's just -- I -- I'm -- I mean I'm</p> <p>9 not --</p> <p>10 Dr. Reed is expressing his view on -- on</p> <p>11 the -- on those -- those NHS data. I have no basis to</p> <p>12 know one way or the other how good those data are.</p> <p>13 Q. So you have no basis to know one way or</p> <p>14 the --</p> <p>15 A. So I'm using their -- their data to get an</p> <p>16 idea of what the -- what the rates -- what the rates</p> <p>17 were, and those are the values that they reported.</p> <p>18 Q. Did you investigate whether there is</p> <p>19 complete reporting among hospitals in the NHS?</p> <p>20 A. No.</p> <p>21 Q. You simply assumed that there was complete</p> <p>22 reporting.</p> <p>23 A. I assume -- I assumed that the data --</p> <p>24 I mean the data are what they are.</p> <p>25 Q. You also assumed that hospitals that use the</p>	<p style="text-align: right;">Page 240</p> <p>1 down the specific devices that they use and if they</p> <p>2 use alternative devices.</p> <p>3 Q. You said you reviewed Dr. Reed's testimony;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. You didn't see in Dr. Reed's deposition</p> <p>7 where he made clear that there are hospitals that use</p> <p>8 both the Bair Hugger and conductive warming devices?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question, lack of foundation, assumes facts not in</p> <p>11 evidence.</p> <p>12 A. I don't know what he was referring to. I</p> <p>13 don't know if he was looking at the same data set that</p> <p>14 I was looking at.</p> <p>15 Q. Okay. Did you investi --</p> <p>16 A. So I don't know.</p> <p>17 Q. Did you investigate to see whether or not</p> <p>18 hospitals do use both devices beyond the documents</p> <p>19 that 3M provided you?</p> <p>20 A. I -- I didn't get any further information.</p> <p>21 I mean it wouldn't surprise me that -- that some</p> <p>22 hospitals -- I mean I don't --</p> <p>23 I don't know if this is exhaustive of all of</p> <p>24 the hospitals or just those that -- that -- that were</p> <p>25 indicated as having used Bair Hugger devices.</p>

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<p>1 Q. Did you ask 3M for more information as to</p> <p>2 whether the data that they provided, which showed that</p> <p>3 some hospitals used the Bair Huggers, may also use</p> <p>4 other devices?</p> <p>5 A. I didn't -- was not provided with any data</p> <p>6 that indicated whether other devices were used by</p> <p>7 any --</p> <p>8 Q. Did you ask them whether or not --</p> <p>9 A. Well my understanding was when it was given,</p> <p>10 that those were using the Bair Hugger.</p> <p>11 Q. And you also just testified that it may very</p> <p>12 well be that they used other devices as well; correct?</p> <p>13 A. Well I don't --</p> <p>14 I didn't compare this to the list of all</p> <p>15 hospitals in the U.K.</p> <p>16 Q. Understood. But --</p> <p>17 A. So there may be hospitals outside of this</p> <p>18 data set, and there is an issue -- issue there that I</p> <p>19 cannot -- you know, cannot speak to.</p> <p>20 Q. But you recognize that other hospitals may</p> <p>21 use --</p> <p>22 A. It's possible.</p> <p>23 Q. -- devices in addition to the Bair Hugger.</p> <p>24 A. Sure. Yes.</p> <p>25 Q. And if that is true, the statistic of an</p>	<p>1 2015.</p> <p>2 A. Yeah. I -- I mean maybe it was, or these --</p> <p>3 That decrease changing the accuracy would go</p> <p>4 to the reporting, as you said, that Dr. Reed reported</p> <p>5 that it's notoriously inaccurately reported, so maybe,</p> <p>6 yeah. I don't know what the magnitude of the</p> <p>7 difference is. I -- I --</p> <p>8 To answer your question specifically, I did</p> <p>9 not review that document.</p> <p>10 Q. Okay. To the extent that you argue that the</p> <p>11 infection rate was .6 percent from 2010 to 2015, what</p> <p>12 is your basis for determining that it is related to</p> <p>13 the Bair Hugger as opposed to the other SSI</p> <p>14 intervention practices that were incorporated in these</p> <p>15 hospitals during that time?</p> <p>16 MR. GORDON: Objection, object to the form,</p> <p>17 and also misconstrues his testimony.</p> <p>18 A. You know, I -- it's -- I mean I --</p> <p>19 It's just using the values that they're --</p> <p>20 they're using. The data that we had -- that I had</p> <p>21 was -- did not provide information other than, as --</p> <p>22 as I've said, that these were hospitals using Bair</p> <p>23 Hugger and this was their infection rate. I don't</p> <p>24 have information on -- on what other SSI methods they</p> <p>25 might happen to have been using.</p>
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<p>1 infection rate of .6 from 2010 to 2015 may or may not</p> <p>2 be attributable just to the Bair Hugger.</p> <p>3 A. It depends on the act -- the degree to</p> <p>4 which, which is -- is true, that they only used one</p> <p>5 device and not the other.</p> <p>6 Q. And you don't know that degree of accuracy.</p> <p>7 A. I don't know the degree of accuracy. That</p> <p>8 was not part of the data that I was provided as -- as</p> <p>9 to measure.</p> <p>10 Q. And you didn't ask for that data.</p> <p>11 A. No.</p> <p>12 Q. To the extent you argue that the infection</p> <p>13 rate from 2010 to 2015 was .6 percent, are you aware</p> <p>14 that there was a significant decrease in deep joint</p> <p>15 infections in the NHS from 2013 to 2015?</p> <p>16 A. I didn't have data specifically relating to</p> <p>17 these.</p> <p>18 Q. So you did not review the Public Health of</p> <p>19 England's report entitled "Surveillance of Surgical</p> <p>20 Site Infections in NHS Hospitals in England?"</p> <p>21 A. No.</p> <p>22 Q. Okay. So you're not aware that, according</p> <p>23 to that document, there was a significant decrease in</p> <p>24 the years of 2013 to '14 and 2014 to '15 and 2014 to</p> <p>25 fif -- '15 -- I said that twice -- but from 2013 to</p>	<p>1 Q. Okay. You also argue that there is no</p> <p>2 reason provided for why the McGovern authors started</p> <p>3 the study period on July 1st, 2008; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And you go on to argue that had the authors</p> <p>6 began the study just one month earlier, the data would</p> <p>7 show a change from significance to non-significance;</p> <p>8 correct?</p> <p>9 A. Using the chi-square test, yes.</p> <p>10 Q. And again you assume, based on that</p> <p>11 calculation as provided in the figures attached to</p> <p>12 your report, that you had complete information with</p> <p>13 respect to infection data prior to July 1st, 2008;</p> <p>14 correct?</p> <p>15 A. That's based on the Albright 10 -- Exhibit</p> <p>16 10 data, yeah.</p> <p>17 Q. And we've discussed that document.</p> <p>18 A. Yes, uh-huh.</p> <p>19 Q. And are you aware that Mr. Reed -- Dr. Reed</p> <p>20 has testified that there was not full surveillance at</p> <p>21 Wansbeck Hospital prior to July 1st, 2008?</p> <p>22 A. Yes. I'm aware that he said that, yeah.</p> <p>23 Q. Are you aware that he said that if one were</p> <p>24 to look at data prior to the study period, there would</p> <p>25 be, quote, big gaps in the period, end quote?</p>

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<p>1 A. That's -- that's -- that's what he reported.</p> <p>2 Q. Are you aware that Dr. Reed also testified</p> <p>3 that to rely on data prior to July 1st, 2008 would be,</p> <p>4 quote, very unreliable, end quote?</p> <p>5 A. That's what he reported.</p> <p>6 I mean related to this, I mean there's a --</p> <p>7 there was a review of -- of the procedures that they</p> <p>8 were using that's referred to in one of the other</p> <p>9 papers --</p> <p>10 What is the author? Starts with a G.</p> <p>11 Gissell?</p> <p>12 Q. Gillson.</p> <p>13 A. Gillson. Thank you.</p> <p>14 -- that this was all not reviewed until</p> <p>15 December, so I'm not sure where -- what Reed is</p> <p>16 referring to.</p> <p>17 Q. So you don't believe Dr. Reed's testimony</p> <p>18 that full surveillance began on Septem -- on July 1st,</p> <p>19 2008.</p> <p>20 A. Well he's -- he's depending on his</p> <p>21 recollection, --</p> <p>22 Q. Okay.</p> <p>23 A. -- I assume, in his deposition.</p> <p>24 Q. Uh-huh.</p> <p>25 A. And I mean that's what he's -- what -- what</p>	<p>1 provided. These were the data that I had available to</p> <p>2 me.</p> <p>3 Q. But --</p> <p>4 So I just want to be clear. Based on what</p> <p>5 you just said, it's either possible that full</p> <p>6 surveillance began on July 1st, 2008 or --</p> <p>7 A. Yes.</p> <p>8 Q. -- perhaps even January 1st, 2009, --</p> <p>9 A. So what --</p> <p>10 Yeah.</p> <p>11 Q. -- but you nonetheless constructed your</p> <p>12 model on data that was prior to that time; correct?</p> <p>13 A. That's -- that's right.</p> <p>14 Q. And that data --</p> <p>15 A. And --</p> <p>16 Q. -- may or may not be complete.</p> <p>17 A. And --</p> <p>18 Q. Answer the question, please.</p> <p>19 A. Well according to Reed's testimony, if</p> <p>20 Reed's correct, if -- if -- if this is correct, that</p> <p>21 might be true.</p> <p>22 Q. Okay.</p> <p>23 A. The other thing that's true, then, if that's</p> <p>24 what in fact took place, is that six months -- or</p> <p>25 whatever it is -- six months or so of McGovern is not</p>
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<p>1 he said in his -- in his deposition; however, that</p> <p>2 seems to not correspond in a peer-reviewed paper what</p> <p>3 was said about when this was all reviewed.</p> <p>4 Q. So is your statement that in the Gillson</p> <p>5 article the authors there represented that the full</p> <p>6 surveillance began in December of 2008?</p> <p>7 A. It was reviewed in December.</p> <p>8 Q. Reviewed in December. But you have no</p> <p>9 knowledge --</p> <p>10 A. I don't --</p> <p>11 Q. -- as to whether --</p> <p>12 A. It doesn't say when it was implemented, --</p> <p>13 Q. Okay.</p> <p>14 A. -- but that would imply, if it was not</p> <p>15 reviewed until December, that it would have been not</p> <p>16 implemented until maybe January. Right? I mean if</p> <p>17 it's not --</p> <p>18 Q. January '09?</p> <p>19 A. '09. Yeah.</p> <p>20 Q. Okay. So if full surveillance wasn't</p> <p>21 implemented until January '09, --</p> <p>22 A. Yes.</p> <p>23 Q. -- you're relying on data from July -- prior</p> <p>24 to July 2008.</p> <p>25 A. These were the data that were -- were</p>	<p>1 reporting appropriately.</p> <p>2 Q. So if this document from the NHS says that</p> <p>3 since July 2008 hospitals are required to have sys --</p> <p>4 systems in place to identify patients who are included</p> <p>5 in the surveillance and later admitted to hospitals</p> <p>6 with an SSI, would that clarify any doubt as to when</p> <p>7 full surveillance began in the NHS?</p> <p>8 MR. GORDON: Object to the form of the</p> <p>9 question, lack of foundation.</p> <p>10 A. Well there is --</p> <p>11 I mean you're -- you're raising questions</p> <p>12 about how accurate the data were recorded, but I mean</p> <p>13 all of these change -- changes took place during the</p> <p>14 McGovern study.</p> <p>15 Q. If Mr. Reed's testimony is true -- if Dr.</p> <p>16 Reed's testimony is true --</p> <p>17 MR. SACCHET: I just said "mister,"</p> <p>18 but I --</p> <p>19 (Discussion off the stenographic record.)</p> <p>20 Q. Okay. If Mr. Reed's testimony is that full</p> <p>21 surveillance began on July 1st, 2008, that is the</p> <p>22 start of the Bair Hugger period in the McGovern study;</p> <p>23 correct?</p> <p>24 A. That's --</p> <p>25 According to his deposition, that -- that's</p>

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<p>1 what it corresponds to, yes.</p> <p>2 Q. And you have no evidence to doubt that, do</p> <p>3 you, Professor Holford?</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question.</p> <p>6 A. I mean the evidence to doubt it is that</p> <p>7 seems to be somewhat contradictory to what Gillson</p> <p>8 says, but I mean I -- I'm not going to -- you know, I</p> <p>9 don't -- I'm -- I'm --</p> <p>10 I'll -- I'll take -- I'll take him at his</p> <p>11 word.</p> <p>12 Q. Okay. And taking him at his word, full</p> <p>13 surveillance starts on July 1st, 2008.</p> <p>14 A. That's what he said.</p> <p>15 Q. Yes.</p> <p>16 (Exhibit 24 was marked for</p> <p>17 identification.)</p> <p>18 BY MR. SACCHET:</p> <p>19 Q. Professor Holford, is this the Gillson</p> <p>20 article that you are referring to that was cited in</p> <p>21 your report?</p> <p>22 A. Is this it? I don't think it is.</p> <p>23 Q. Okay. Let me --</p> <p>24 A. I -- let's see.</p> <p>25 MR. SACCHET: I may have marked the wrong</p>	<p>1 MR. SACCHET: Yeah, it's the Brister</p> <p>2 article.</p> <p>3 THE WITNESS: Yeah, okay. Yeah. I didn't</p> <p>4 think this was Gillson, that's all. See, Gillson</p> <p>5 is -- where are we -- same journal, 2014, June '17.</p> <p>6 Is that true? That was --</p> <p>7 Oh, no. It was published in 21 -- 2011.</p> <p>8 Yeah, that's Brister.</p> <p>9 MR. SACCHET: Yeah.</p> <p>10 THE WITNESS: Yeah.</p> <p>11 (Exhibit 25 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. Is this the Gillson article that you were</p> <p>15 referring to?</p> <p>16 A. Yes, it is.</p> <p>17 Q. Okay.</p> <p>18 A. Yes.</p> <p>19 Q. Can you point me to any particular statement</p> <p>20 in this article where there's information that</p> <p>21 contradicts Mr. Reed's testimony?</p> <p>22 A. Oh. There's a figure somewhere in there,</p> <p>23 which is practically illegible in this copy --</p> <p>24 Q. I don't want to spend tons of time on this,</p> <p>25 professor, but --</p>
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<p>1 document, professor. Is it -- I just --</p> <p>2 I'll shortcut this because I think I might</p> <p>3 have. Is the first line of the document you're</p> <p>4 looking at actually from Brister, not Gillson?</p> <p>5 MR. GORDON: Yeah.</p> <p>6 MR. SACCHET: I may have given you the wrong</p> <p>7 one.</p> <p>8 MR. GORDON: That's what you want to give</p> <p>9 him.</p> <p>10 MR. SACCHET: Okay.</p> <p>11 THE WITNESS: Yeah. I think this is one of</p> <p>12 the ones that --</p> <p>13 MR. SACCHET: Yeah. That's my fault.</p> <p>14 THE WITNESS: Yeah. It's strange, because</p> <p>15 the author is not -- doesn't appear on it, which is</p> <p>16 kind of a --</p> <p>17 MR. SACCHET: The author is there on the</p> <p>18 top, it's just --</p> <p>19 It's my fault.</p> <p>20 THE WITNESS: Okay. Yeah. It was hard to</p> <p>21 find the author on this one, that's what -- yeah.</p> <p>22 Anyway --</p> <p>23 MR. GORDON: This is al --</p> <p>24 This Exhibit 24 is on his list of</p> <p>25 references, it's just --</p>	<p>1 A. I've got a --</p> <p>2 Q. -- one thing that might be helpful is you</p> <p>3 would agree, wouldn't you, that this particular</p> <p>4 document relates to Northumbria Healthcare; correct?</p> <p>5 A. That includes Wansbeck, yeah.</p> <p>6 Q. But it's not specific to Wansbeck; correct?</p> <p>7 A. That -- that's correct.</p> <p>8 Q. So even if, for the sake of argument, this</p> <p>9 document said something to the effect that there was a</p> <p>10 different time in which full surveillance occurred,</p> <p>11 that may or may not be specific to Wansbeck.</p> <p>12 A. Well I assume it would include Wansbeck.</p> <p>13 I -- I don't know how they operate, but -- yeah.</p> <p>14 Q. It's possible that Wansbeck may have been</p> <p>15 ahead of the curve with respect to what NHS did as a</p> <p>16 trust; correct?</p> <p>17 A. I -- I guess that's possible.</p> <p>18 Q. Okay. So even if there's a date in this</p> <p>19 document that's specific to NHS, it does not</p> <p>20 contradict Mr. Reed's testimony.</p> <p>21 A. Not necessarily.</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, --</p> <p>24 A. Well --</p> <p>25 MR. GORDON: -- assumes facts not in</p>

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<p>1 evidence.</p> <p>2 A. --it may or may not. I don't know.</p> <p>3 Q. Well let's just do an example. If this</p> <p>4 document said that the NHS implemented full-scale</p> <p>5 surveillance of DJI in 2015 -- which it doesn't, but</p> <p>6 for the sake of argument assume that to be true --</p> <p>7 A. Yeah. Well it --</p> <p>8 MR. GORDON: Wait, wait.</p> <p>9 A. It's -- it's talking about --</p> <p>10 MR. GORDON: Wait, wait. Is there --</p> <p>11 I don't think he was done with his question.</p> <p>12 MR. SACCHET: I'm not. Thank you.</p> <p>13 Q. -- even if there was such a suggestion in</p> <p>14 this paper, that does not preclude the possibility</p> <p>15 that Wansbeck started full-scale surveillance for</p> <p>16 itself on July 1st, 2008.</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, also assumes facts not in evidence.</p> <p>19 A. I -- I don't --</p> <p>20 This is dealing with, as I understand it, as</p> <p>21 I recall, Northumbria, --</p> <p>22 Q. Yeah.</p> <p>23 A. -- which includes, what, about three</p> <p>24 hospitals I think.</p> <p>25 Q. Three hospitals, that's correct.</p>	<p>1 know, what, seven or eight years ago. It seems</p> <p>2 possible that he misremem -- didn't remember it quite</p> <p>3 right.</p> <p>4 Q. Well this document was published in 2014;</p> <p>5 correct? October for that matter.</p> <p>6 A. Yeah, but -- well it -- this is a --</p> <p>7 Gillson and Lowdon were writing this in the</p> <p>8 leisure of their office. They weren't under</p> <p>9 deposi -- under pressure of being under a</p> <p>10 deposition --</p> <p>11 Q. Okay.</p> <p>12 A. --- and having to come up with answers off</p> <p>13 the top of your head.</p> <p>14 Q. Okay. So let's just --</p> <p>15 I think we need to cut to it. There's</p> <p>16 nothing in this doc -- document that necessarily</p> <p>17 contradicts Mr. Reed's testimony.</p> <p>18 A. It may not.</p> <p>19 Q. It may not.</p> <p>20 A. Yeah. It -- it --</p> <p>21 Yeah, it may or may not. I --</p> <p>22 Q. Is there any other evidence you relied on,</p> <p>23 apart from that document, to surmise that there was</p> <p>24 full reporting before July 1st, 2008 or after July</p> <p>25 1st, 2008?</p>
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<p>1 A. And one of them being Wansbeck.</p> <p>2 Q. That's correct.</p> <p>3 A. And so if they're making a policy with --</p> <p>4 with regard to their group of hospitals, then I</p> <p>5 would --</p> <p>6 Was what you're suggesting is Wansbeck is</p> <p>7 going outside of their --</p> <p>8 Q. Ahead of the curve.</p> <p>9 A. It's -- I guess it's conceivable.</p> <p>10 Q. That's how law works with respect to the</p> <p>11 federal government and states; correct? States can</p> <p>12 implement rights that are more progressive than what</p> <p>13 the federal government has promulgated; correct?</p> <p>14 A. They -- they can. Whether hospitals --</p> <p>15 hospital groups function that much, I -- I just don't</p> <p>16 know that much about the hospitals in -- in -- in the</p> <p>17 U.K.</p> <p>18 Q. Okay.</p> <p>19 A. I mean this took place in, what was it,</p> <p>20 2008, '10, in that area, and when was Reed's</p> <p>21 testimony?</p> <p>22 Q. His deposition testimony?</p> <p>23 A. His deposi -- yeah.</p> <p>24 Q. 2016.</p> <p>25 A. '16. So I mean he's recalling things, you</p>	<p>1 A. Well these -- these data -- I mean that --</p> <p>2 The Albrecht 10, as I understand it, was not</p> <p>3 the routine way in which a lot of these data were</p> <p>4 collected, that they had to go back to the hospitals</p> <p>5 and add a lot of the variables that they did, and so</p> <p>6 in doing that, well, they went back to -- what was</p> <p>7 it --</p> <p>8 Q. Sometime in 2007.</p> <p>9 A. -- sometime in 2007, whatever it was, well</p> <p>10 before Mr. July 2008.</p> <p>11 Q. But based on Mr. Reed's testimony, you do</p> <p>12 not know --</p> <p>13 A. Based on the testimony --</p> <p>14 Q. -- whether it was a complete data set prior</p> <p>15 to July 1st, 2008. You don't know.</p> <p>16 A. Well was he talking about Albrecht 10? I</p> <p>17 don't know.</p> <p>18 Q. I'm talking about reconstruct --</p> <p>19 A. I know what you're talking about, --</p> <p>20 Q. Yeah.</p> <p>21 A. -- but I'm not sure what Reed is talking</p> <p>22 about.</p> <p>23 Q. Talking about Wansbeck Hospital; correct?</p> <p>24 A. Okay. But he --</p> <p>25 MR. GORDON: Object to the form of the</p>

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<p style="text-align: right;">Page 257</p> <p>1 question.</p> <p>2 A. Was he talking about the data in Albrecht</p> <p>3 10? I just -- I don't remember, frankly.</p> <p>4 Q. Okay. Did you make any inquiry separate and</p> <p>5 apart from the Gillson document about when full</p> <p>6 reporting began at Wansbeck?</p> <p>7 A. No.</p> <p>8 Q. And you didn't ask 3M for any documents on</p> <p>9 the subject matter.</p> <p>10 A. No.</p> <p>11 Q. And they provided no such documents on the</p> <p>12 subject matter.</p> <p>13 A. Not of when the -- on the -- on those</p> <p>14 procedures, yeah.</p> <p>15 Q. Okay.</p> <p>16 A. They didn't.</p> <p>17 Q. So your opinion as to the table that you</p> <p>18 provided is based on Albrecht Exhibit 10 and that's</p> <p>19 it.</p> <p>20 A. That's right.</p> <p>21 Q. Okay. With respect to Fig. 2, you provide</p> <p>22 time trend data and there is a moving average line</p> <p>23 which is the solid blue line; correct?</p> <p>24 A. Yes.</p> <p>25 Q. And that line -- or that data also begins in</p>	<p style="text-align: right;">Page 259</p> <p>1 the data file.</p> <p>2 Q. In Albrecht Exhibit 10.</p> <p>3 A. Yes.</p> <p>4 Q. And the green line is the constant average</p> <p>5 of deep joint infection in the Bair Hugger period and</p> <p>6 the Hot Dog period; correct?</p> <p>7 A. That's right.</p> <p>8 Q. And that is also based on Albrecht Exhibit</p> <p>9 10; correct?</p> <p>10 A. Yes.</p> <p>11 Q. So instead of an infection rate of 3.0, your</p> <p>12 infection rate with respect to the Bair Hugger period</p> <p>13 is 2.91.</p> <p>14 A. Something like that.</p> <p>15 Q. Okay.</p> <p>16 A. Looks about right.</p> <p>17 Q. And the Hot Dog rate, instead of being .8</p> <p>18 percent, is 1.08 percent; correct?</p> <p>19 A. That sounds about right, and it looks about</p> <p>20 right from the -- from the graph.</p> <p>21 Q. And that's based on using four Hot Dog</p> <p>22 infections instead of three Hot Dog infections;</p> <p>23 correct?</p> <p>24 A. That's correct.</p> <p>25 Q. And that derives from Albrecht Exhibit 10;</p>
<p style="text-align: right;">Page 258</p> <p>1 2007; correct?</p> <p>2 A. That's right.</p> <p>3 Q. And it begins on September 1st, 2007, which</p> <p>4 is approximately 10 months before the McGovern study</p> <p>5 period; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And that data also depends on Albrecht</p> <p>8 Exhibit 10; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And with respect to the first spike in this</p> <p>11 figure, if you took away the data prior to July 1st,</p> <p>12 2008, wouldn't be much of a spike; correct?</p> <p>13 A. Well it's sort of -- yeah. In the earlier</p> <p>14 data there was really very little going on, the rates</p> <p>15 were very, very low. Bair Hugger was being used, as I</p> <p>16 understand it, but the infection rates were extremely</p> <p>17 low.</p> <p>18 Q. And to the extent that there was incomplete</p> <p>19 data prior to July 2007, that would explain the low</p> <p>20 rates; correct?</p> <p>21 MR. GORDON: Objection, assumes facts not in</p> <p>22 evidence.</p> <p>23 A. I mean the reason there were no -- there</p> <p>24 were very few in -- infections -- I mean I don't -- I</p> <p>25 don't know. There were very few reported in the -- in</p>	<p style="text-align: right;">Page 260</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay.</p> <p>4 MR. GORDON: Well --</p> <p>5 Q. The broken blue line --</p> <p>6 A. Well it depends on --</p> <p>7 I mean the four also comes from the -- from</p> <p>8 the deposition by Reed where he reports that there was</p> <p>9 one more in -- one more infection for --</p> <p>10 Well, he reports one more in each group.</p> <p>11 Q. Okay. But you don't ever, aside from</p> <p>12 footnote one, assume that there is one more infection</p> <p>13 in the Bair Hugger period; correct?</p> <p>14 MR. GORDON: Object to the --</p> <p>15 A. That's --</p> <p>16 Well I -- I mean I used -- used Exhibit 10.</p> <p>17 Q. Yes. But you just --</p> <p>18 A. I mean, again, we've been talking about</p> <p>19 Reed --</p> <p>20 Q. Uh-huh.</p> <p>21 A. -- and it seems quite possible that Reed</p> <p>22 was, you know, retrospectively recalling what took</p> <p>23 place, --</p> <p>24 Q. Uh-huh. And Reed --</p> <p>25 A. -- and so he said there was one more.</p>

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<p style="text-align: right;">Page 261</p> <p>1 Q. Uh-huh.</p> <p>2 A. Well, I wouldn't accuse him of lying if</p> <p>3 there in fact was one more in one group and one less</p> <p>4 in the other.</p> <p>5 Q. Okay. If you wouldn't accuse him of lying,</p> <p>6 you didn't rely on those numbers at any place in your</p> <p>7 report other than footnote one; correct?</p> <p>8 A. Other than footnote -- footnote one, yeah.</p> <p>9 Footnote one is basically where I --</p> <p>10 Q. That's the full extent.</p> <p>11 A. That's right. I took -- I took -- took him</p> <p>12 at his word and --</p> <p>13 Q. Okay.</p> <p>14 A. -- used those values.</p> <p>15 Q. So with respect to the statement you made</p> <p>16 prior to that, you're relying on Reed with respect to</p> <p>17 four Hot Dog infections but not 32 or 33 Bair Hugger</p> <p>18 infections, only 31 Bair Hugger infections.</p> <p>19 A. Well the numbers -- the numbers that were</p> <p>20 used in that tabulation were the numbers that I got</p> <p>21 from -- from the -- from Albright 10 --</p> <p>22 Q. Yeah.</p> <p>23 A. -- and --</p> <p>24 Q. Which is inconsistent with Reed's testimony;</p> <p>25 correct?</p>	<p style="text-align: right;">Page 263</p> <p>1 Q. Okay.</p> <p>2 A. -- things quite right.</p> <p>3 Q. But with respect to the four infections and</p> <p>4 33 infections, that might be true, but it may not be</p> <p>5 true that the start date was July 1st, 2008.</p> <p>6 A. Yeah. I mean if he mis -- if he</p> <p>7 misremembered one, it's possible he misremembered the</p> <p>8 other as well.</p> <p>9 Q. Okay.</p> <p>10 A. I mean I -- I don't know.</p> <p>11 Q. But you don't know.</p> <p>12 A. I --</p> <p>13 No, I don't know. I don't know. If you</p> <p>14 asked me what I was doing --</p> <p>15 Q. Yeah.</p> <p>16 A. -- in July 2008, I don't think I could tell</p> <p>17 you very accurately.</p> <p>18 Q. Had you relied on Reed's testimony regarding</p> <p>19 the four infections in the Hot Dog group and the 33</p> <p>20 infections in the Bair Hugger group, all of the</p> <p>21 calculations in your report would be different;</p> <p>22 correct?</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question, assumes facts not in evidence.</p> <p>25 A. Yeah. I'm not sure what --</p>
<p style="text-align: right;">Page 262</p> <p>1 A. It's inconsistent.</p> <p>2 Q. Yeah.</p> <p>3 A. Yeah. It's the -- it's -- it's --</p> <p>4 I think it's the same for Hot Dog, but it's</p> <p>5 inconsistent for Bair Hugger.</p> <p>6 Q. Well Reed says four infections Hot Dog, 33</p> <p>7 infections Bair Hugger; correct? One more in each</p> <p>8 group.</p> <p>9 A. That's what -- that's what he said.</p> <p>10 Q. Yeah.</p> <p>11 A. Yeah.</p> <p>12 Q. And the --</p> <p>13 A. But -- but the tab -- but --</p> <p>14 But Albright 10 --</p> <p>15 Q. Yeah.</p> <p>16 A. -- says four and 31.</p> <p>17 Q. But you wouldn't assume, like you just said,</p> <p>18 that Reed would be lying; right?</p> <p>19 A. No. I just -- I -- I would guess that</p> <p>20 he's -- that he's not remembering things. I mean as</p> <p>21 we -- as you notice, he's reporting on -- he's talking</p> <p>22 about something in his deposition about eight --</p> <p>23 Q. Yeah.</p> <p>24 A. -- seven or eight years later, and he may</p> <p>25 not remember --</p>	<p style="text-align: right;">Page 264</p> <p>1 Q. I can re -- I'll rephrase.</p> <p>2 Your calculation derives from four Hot Dog</p> <p>3 infections and 31 Bair Hugger infections; correct?</p> <p>4 A. Yeah. Well, which derives from Albrecht 10.</p> <p>5 Q. Albrecht 10.</p> <p>6 A. Yes.</p> <p>7 Q. And there's no reason to suspect that Reed</p> <p>8 was lying. He testified that there was four Hot Dog</p> <p>9 infections and 33 Bair Hugger infections, and if that</p> <p>10 is true, that would change all of the calculations in</p> <p>11 your report; correct?</p> <p>12 A. It would change many of them. I mean</p> <p>13 ideally what I would like to know is why -- what --</p> <p>14 what the correct --</p> <p>15 While Reed may not remember exactly what</p> <p>16 took place, what -- what the -- what the values were,</p> <p>17 I think he's -- he's suggesting that there -- there</p> <p>18 was an error in the data that are published in</p> <p>19 McGovern.</p> <p>20 Q. And assuming that to be true, one of those</p> <p>21 errors is actually there was more Bair Hugger</p> <p>22 infections.</p> <p>23 A. And more -- I mean he --</p> <p>24 One of the things he is conceding is that</p> <p>25 there is more -- there -- there's one more Hot Dog</p>

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<p style="text-align: right;">Page 265</p> <p>1 infection.</p> <p>2 Q. But you took into account --</p> <p>3 A. Because there's -- because there's so few,</p> <p>4 there's only three, --</p> <p>5 Q. Yeah.</p> <p>6 A. -- you're going from three to four, so</p> <p>7 that's a 33 percent difference, so that's having a</p> <p>8 much bigger effect on your estimates of risk than the</p> <p>9 change of one or two in the -- in the -- in the Bair</p> <p>10 Hugger.</p> <p>11 Q. But you never used that data with respect to</p> <p>12 the Bair Hugger; correct?</p> <p>13 MR. GORDON: Objection.</p> <p>14 Q. You only used the four hundred -- or the</p> <p>15 four Hot Dog infections and only used 33 Bair Hugger</p> <p>16 infections in footnote one of your report; correct?</p> <p>17 A. That's the only place -- that's the only</p> <p>18 place I -- I change it in my report.</p> <p>19 Q. Okay.</p> <p>20 A. Yeah.</p> <p>21 Q. Okay.</p> <p>22 A. I mean ideally what I would like to know, as</p> <p>23 this implies, that there is -- that -- for Albrecht</p> <p>24 10, and to be consistent, I would like to get it</p> <p>25 consistent with -- with Reed.</p>	<p style="text-align: right;">Page 267</p> <p>1 A. That neither one was right?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, assumes facts not in evidence, calls for</p> <p>4 speculation.</p> <p>5 Q. I mean the published data is neither one of</p> <p>6 those two. Correct?</p> <p>7 A. It's neither one of them.</p> <p>8 MR. GORDON: Same objection.</p> <p>9 Q. Right. It's -- it's neither Albrecht 10 --</p> <p>10 A. Oh, I see. Yeah.</p> <p>11 Q. -- nor Reed's testimony.</p> <p>12 A. Yeah. I mean if it's -- yeah, if you're</p> <p>13 going --</p> <p>14 Q. On the published data.</p> <p>15 A. Yeah. If the published data is -- is</p> <p>16 correct --</p> <p>17 Q. Okay.</p> <p>18 A. -- and there's -- I mean, you know, there's</p> <p>19 some doubt, obviously, but --</p> <p>20 Q. Let's move to the confounding portion of</p> <p>21 your report. And I'd like to establish a definition</p> <p>22 of "confounding," which I'll phrase as a variable C is</p> <p>23 a confounder if it is related to disease and also</p> <p>24 related to exposure. Do you agree with that?</p> <p>25 A. State that again.</p>
<p style="text-align: right;">Page 266</p> <p>1 Q. And you can't.</p> <p>2 A. Not as they're given.</p> <p>3 Q. Okay.</p> <p>4 A. They would have to sit down and somehow make</p> <p>5 a correction, either --</p> <p>6 Well either Reed is right or -- or Albrecht</p> <p>7 10 is -- is right on this particular question, and it</p> <p>8 would be good if -- it would be nice if I could sit</p> <p>9 down and they could correct what this -- what</p> <p>10 the -- what the -- what the discrepancy is.</p> <p>11 Q. And you --</p> <p>12 A. There is a discrepancy.</p> <p>13 Q. And you don't know.</p> <p>14 A. And I don't know why there is a discrepancy.</p> <p>15 Q. And you don't know which one it might be.</p> <p>16 A. I don't know. I mean in looking at a file</p> <p>17 that looks like a raw data set gives me at bit more</p> <p>18 confidence than someone remembering something eight</p> <p>19 years ago. But in any event, it needs -- well</p> <p>20 someone --</p> <p>21 Ideally, someone would sit down with these</p> <p>22 data and, you know, review it with the -- with the raw</p> <p>23 records and -- and -- to correct whatever -- whatever</p> <p>24 it is.</p> <p>25 Q. It could also be neither.</p>	<p style="text-align: right;">Page 268</p> <p>1 Q. A variable C is a confounder if it is</p> <p>2 related to disease and also related to exposure.</p> <p>3 A. If -- if it is related to disease and it's</p> <p>4 related to the exposure --</p> <p>5 We're not saying statistically significant;</p> <p>6 right?</p> <p>7 Q. Yeah. I'm just --</p> <p>8 Just for this definition.</p> <p>9 A. Yeah. If that --</p> <p>10 If those are true, then it is a confounder.</p> <p>11 Q. That's how you defined it in your article</p> <p>12 "Confounding in Epidemiological Studies" which was</p> <p>13 published in Biometrics; correct?</p> <p>14 A. Oh. Oh, right, right. Yeah, that's -- I --</p> <p>15 I didn't remember which -- trying to remember which</p> <p>16 article you were talking about. Yeah.</p> <p>17 Q. By Wickramaratne --</p> <p>18 A. Oh, okay.</p> <p>19 Q. -- and you.</p> <p>20 A. Not the --</p> <p>21 Okay. Yeah, yeah, yeah, yeah.</p> <p>22 Q. That's how you defined it.</p> <p>23 A. Okay.</p> <p>24 Q. And according to Dr. Borak, differently</p> <p>25 stated, a variable must be an independent risk factor</p>

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<p style="text-align: right;">Page 269</p> <p>1 for it to be a confounder on the outcome; correct?</p> <p>2 MR. GORDON: Well object, foundation.</p> <p>3 A. Yeah. It needs to be a risk --</p> <p>4 It needs to have an association.</p> <p>5 Q. Okay. And if there's no such association to</p> <p>6 the outcome, it's not a confounder; correct?</p> <p>7 A. That's right. I'm not eliminating it, of</p> <p>8 course.</p> <p>9 Q. Yeah. I know what you said before, but --</p> <p>10 A. Again, I'm not saying --</p> <p>11 Q. -- if there's no a priori relationship, it's</p> <p>12 not a confounder.</p> <p>13 A. Yeah. And we're taking about statis --</p> <p>14 We're not talking about statistics.</p> <p>15 Q. An a priori relationship.</p> <p>16 A. Yeah.</p> <p>17 Q. If there's an a priori --</p> <p>18 If there's not an a priori relationship</p> <p>19 between a variable and an outcome, it's not a</p> <p>20 confounding factor.</p> <p>21 A. That's right. Adjusted for the -- adjusted</p> <p>22 for each other, yeah.</p> <p>23 Q. Okay. Are you aware that thromboprophylaxes</p> <p>24 are used for reducing the risk of blood clotting?</p> <p>25 A. I -- yeah. I think so, yeah. Yeah.</p>	<p style="text-align: right;">Page 271</p> <p>1 Q. You're not aware that tinzaparin is also</p> <p>2 often administered postoperatively.</p> <p>3 A. I didn't know how they were operate -- they</p> <p>4 were --</p> <p>5 Q. You didn't read that in the McGovern study?</p> <p>6 A. I probably did. I wasn't --</p> <p>7 I mean they were using it in the Jensen</p> <p>8 study, they were using it and comparing it and looking</p> <p>9 at it for an effect with -- with infections.</p> <p>10 Q. Understood. But you're aware that the</p> <p>11 McGovern study, the patients received the</p> <p>12 thromboprophylaxis postoperatively.</p> <p>13 A. Okay.</p> <p>14 Q. Okay. So the thromboprophylaxis does not</p> <p>15 add particles to the surgical site; correct?</p> <p>16 A. Presumably not.</p> <p>17 Q. It doesn't add bacteria to the surgical</p> <p>18 site; correct?</p> <p>19 A. No.</p> <p>20 Q. Xarelto is approved by The American College</p> <p>21 of Chest Physicians. Do you know that?</p> <p>22 MR. GORDON: Objection, lack of foundation.</p> <p>23 A. Xarelto is which one now?</p> <p>24 Q. Rivaroxaban.</p> <p>25 A. Rivaroxaban. Okay.</p>
<p style="text-align: right;">Page 270</p> <p>1 Q. The point of using --</p> <p>2 A. Yeah.</p> <p>3 Q. -- a thromboprophylaxis, whether it be</p> <p>4 tinzaparin or Xarelto or any other low-molecular-</p> <p>5 weight heparin, is to reduce the incidence of venous</p> <p>6 thrombosis; right?</p> <p>7 A. Okay. I'm not a clinician, but --</p> <p>8 Q. So you're not a clinician but you're</p> <p>9 assuming there's an a priori relationship between</p> <p>10 thrombo and other outcomes separate and apart from</p> <p>11 deep vein thrombosis?</p> <p>12 A. Well what you're asking for is a -- is a</p> <p>13 particular relationship, which is not --</p> <p>14 I mean there are lots of drugs that are</p> <p>15 related to more than one thing.</p> <p>16 Q. Okay.</p> <p>17 A. So the fact that that's what it is used for</p> <p>18 does not mean it does not -- does or does not have</p> <p>19 another effect.</p> <p>20 Q. Okay. Do you know how thromboprophylaxes</p> <p>21 are administered?</p> <p>22 A. No.</p> <p>23 Q. You're not aware that Xarelto is</p> <p>24 administered postoperatively.</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 272</p> <p>1 Q. It is.</p> <p>2 A. Okay. I don't --</p> <p>3 I was not aware of that. I --</p> <p>4 Q. Okay. Have you studied the record trials?</p> <p>5 A. No, I have not.</p> <p>6 Q. You're not aware that there were five</p> <p>7 randomized controlled trials that evaluated the safety</p> <p>8 of rivaroxaban, otherwise known as Xarelto, in</p> <p>9 orthopedic surgeries?</p> <p>10 A. No, I'm not familiar with that.</p> <p>11 Q. You're not aware that one of the studies</p> <p>12 concluded that the clinical efficacy and safety of</p> <p>13 rivaroxaban after elective hip and knee arthroplasty</p> <p>14 has been established in the four randomized controlled</p> <p>15 trials of the regulation of coagulation in orthopedic</p> <p>16 surgery to prevent deep vein thrombosis.</p> <p>17 A. I was not familiar with that.</p> <p>18 Q. Did you attempt to investigate whether</p> <p>19 thromboprophylaxes have been deemed to be safe in</p> <p>20 orthopedic surgeries?</p> <p>21 A. No. I was -- I was looking at -- well the</p> <p>22 same -- the evidence that -- that McGovern cited as --</p> <p>23 He was citing the -- the work that was done</p> <p>24 by -- the paper by Jensen I believe.</p> <p>25 Q. So the only basis for an a priori assumption</p>

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<p style="text-align: right;">Page 273</p> <p>1 that the use of Xarelto is related to the outcome of</p> <p>2 interest; namely, deep joint infection, is the Jensen</p> <p>3 study?</p> <p>4 A. That was, my understanding, the basis on</p> <p>5 which they did not control for it.</p> <p>6 Q. And my question is a little different. Your</p> <p>7 basis for making an a priori assumption that Xarelto</p> <p>8 is related to the outcome of interest, which is deep</p> <p>9 joint infection, is only the Jensen study.</p> <p>10 A. That's what I was looking -- looking for.</p> <p>11 McGovern did not control for any</p> <p>12 confounding.</p> <p>13 Q. I understand. My question again, which I</p> <p>14 think you answered, is that the only piece of</p> <p>15 evidence --</p> <p>16 A. Yes.</p> <p>17 Q. -- that you considered as to whether there</p> <p>18 is an --</p> <p>19 A. I was --</p> <p>20 Q. -- a priori relationship between Xarelto and</p> <p>21 the outcome of interest, which is deep joint</p> <p>22 infection, is the Jensen study. True or false? It's</p> <p>23 a one-word answer.</p> <p>24 A. Yeah. Well I wasn't saying it was a priori.</p> <p>25 I was looking at the data --</p>	<p style="text-align: right;">Page 275</p> <p>1 not be a confounder is based on the data from Albrecht</p> <p>2 Exhibit 10.</p> <p>3 A. Yes.</p> <p>4 Q. You conducted no investigation to determine</p> <p>5 whether the peer-reviewed public literature had</p> <p>6 determined that Xarelto was safe in orthopedic</p> <p>7 surgeries.</p> <p>8 A. No.</p> <p>9 Q. And the Jensen study, which appears to be</p> <p>10 the source that you rely on with application of</p> <p>11 Albrecht Exhibit 10, in fact found that there was not</p> <p>12 a significant difference between deep joint infection</p> <p>13 rates from the use of Xarelto compared to tinzaparin;</p> <p>14 correct?</p> <p>15 A. They did not find a statistical</p> <p>16 significance.</p> <p>17 Q. That's the scope of the question.</p> <p>18 A. That's right.</p> <p>19 Q. And the p-value wasn't even close to</p> <p>20 significant; correct?</p> <p>21 A. Yes. The p-value was --</p> <p>22 Yeah.</p> <p>23 Q. Do you know what it was?</p> <p>24 A. I think somewhere around .11 or something.</p> <p>25 I don't remember.</p>
<p style="text-align: right;">Page 274</p> <p>1 Q. Okay.</p> <p>2 A. -- to see whether or not there was an</p> <p>3 association.</p> <p>4 Q. Is that the only study that you looked at?</p> <p>5 A. Well I was using --</p> <p>6 I referred to that study because that was</p> <p>7 the study that McGovern referred to.</p> <p>8 Q. Did you look at any other studies?</p> <p>9 A. I didn't look at any other studies. I had</p> <p>10 be --</p> <p>11 The data on which the Jensen paper was --</p> <p>12 was based, I mean the design is basically the same</p> <p>13 sort of --</p> <p>14 Q. The same design as in McGovern.</p> <p>15 A. Yeah. It's the same flawed design that</p> <p>16 McGovern used, which is based on dates.</p> <p>17 Q. Okay. But my question again is did you look</p> <p>18 at any other studies?</p> <p>19 A. And so I could repeat -- I could repeat the</p> <p>20 analysis --</p> <p>21 Q. Okay. We'll get there. Trust me, we'll get</p> <p>22 there.</p> <p>23 A. -- that -- that they did using Albrecht 10.</p> <p>24 Q. Okay. So in other words, your only basis</p> <p>25 for concluding that the thromboprophylaxis may or may</p>	<p style="text-align: right;">Page 276</p> <p>1 Q. .7 ring a bell?</p> <p>2 A. .7?</p> <p>3 Q. Yeah.</p> <p>4 MR. GORDON: Maybe you should look at the</p> <p>5 article.</p> <p>6 A. Yeah. That seems high. I --</p> <p>7 Do you have the article?</p> <p>8 Q. We have marked the article as a prior</p> <p>9 exhibit, and I can tell you what it is in a moment.</p> <p>10 MR. GORDON: I'm look --</p> <p>11 Nineteen.</p> <p>12 A. Here. Oh, I'm --</p> <p>13 MR. GORDON: Exhibit 19.</p> <p>14 Q. If you turn to page 523 on the bottom right,</p> <p>15 or internal page 93, there's a section entitled</p> <p>16 "Results;" correct?</p> <p>17 Of the Jensen study.</p> <p>18 A. Do I have --</p> <p>19 Q. Oh, okay.</p> <p>20 MR. GORDON: It's Exhibit 19.</p> <p>21 Q. Exhibit 19, professor.</p> <p>22 A. Nineteen.</p> <p>23 MR. GORDON: That's it.</p> <p>24 Q. Okay. If you turn to page 523, in the</p> <p>25 bottom right-hand corner --</p>

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<p>1 A. Okay.</p> <p>2 Q. -- on the left column is a section entitled</p> <p>3 "Results;" correct?</p> <p>4 A. Yes.</p> <p>5 Q. Do you see the third paragraph that says,</p> <p>6 "Of those...?"</p> <p>7 A. Yeah.</p> <p>8 Q. It says, "Of those patients who returned to</p> <p>9 theatre, microbiology results showed that five of the</p> <p>10 nine (55.5 percent) in group 1 had a deep infection,</p> <p>11 compared with 14 of 22 (63.6 percent) in group 2 (p</p> <p>12 equals 0.7)."</p> <p>13 A. Okay.</p> <p>14 Q. Does that refresh your recollection --</p> <p>15 MR. GORDON: Well why don't you read the</p> <p>16 rest of the section that actually talks about deep</p> <p>17 infection.</p> <p>18 THE WITNESS: Yeah.</p> <p>19 Q. "The overall rate of deep infection in group</p> <p>20 1 was one percent, compared with 2.5 percent in group</p> <p>21 2" with a p-value of .1.</p> <p>22 A. Right. So that's what I was --</p> <p>23 Q. Is that the p-value of interest or is it the</p> <p>24 .7?</p> <p>25 A. I was thinking it was --</p>	<p>1 A. Exactly.</p> <p>2 Q. Okay. In addition to the Jensen study, did</p> <p>3 you review the Reed study that also analyzed whether</p> <p>4 there was a significant increase in deep joint</p> <p>5 infection rates from the use of a low-molecular-weight</p> <p>6 heparin to Xarelto?</p> <p>7 A. I don't know that I looked at that much.</p> <p>8 Q. It was cited by Dr. Samet; correct?</p> <p>9 A. It -- it may have been. I -- I'm just not</p> <p>10 re --</p> <p>11 I don't recall that one.</p> <p>12 Q. I'll represent to you that it was cited</p> <p>13 by --</p> <p>14 A. Okay.</p> <p>15 Q. -- Dr. Samet. You did not review that</p> <p>16 article?</p> <p>17 A. I don't recall reviewing that article, no.</p> <p>18 Q. So to the extent that Dr. Samet relied on</p> <p>19 that article in concluding that the change in</p> <p>20 thromboprophylaxis was not a confounding factor, you</p> <p>21 have not reviewed that study and therefore cannot</p> <p>22 comment on it.</p> <p>23 A. Well Samet was talking about looking at</p> <p>24 effects and he was basing his conclusions on the</p> <p>25 conclusion of the paper, which depended on statistical</p>
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<p>1 You're com -- you're comparing the deep</p> <p>2 infection rate --</p> <p>3 Q. Okay.</p> <p>4 A. -- between the two, and so that was the</p> <p>5 comparison that I was looking at, because we were</p> <p>6 looking at deep -- you know, deep infection rates in</p> <p>7 McGovern.</p> <p>8 And of course the definition of "deep</p> <p>9 infection" is different in Jensen's paper than it is</p> <p>10 in McGovern.</p> <p>11 Q. It was a 30-day period whereas in --</p> <p>12 A. Thirty days --</p> <p>13 Q. -- McGovern it was a 60-day period; correct?</p> <p>14 A. Exactly.</p> <p>15 Q. Okay.</p> <p>16 A. So there are some -- going to be some more</p> <p>17 infections in -- if -- I -- I --</p> <p>18 I went on and I used the McGovern</p> <p>19 definition.</p> <p>20 Q. Yeah. For both arms of the study; correct?</p> <p>21 A. For -- for -- that's right, for the -- for</p> <p>22 Jensen.</p> <p>23 Q. So there could be more infections in the</p> <p>24 Bair Hugger group and there could be more infections</p> <p>25 in the Hot Dog group.</p>	<p>1 significance, --</p> <p>2 Q. Okay.</p> <p>3 A. -- so he was looking at --</p> <p>4 My understanding of Samet's statement was</p> <p>5 on -- the basis of it was that they did not find that</p> <p>6 it was statistically significant, --</p> <p>7 Q. Okay.</p> <p>8 A. -- and on that basis he -- he dismissed it.</p> <p>9 Q. To the extent that others have concluded,</p> <p>10 such as Dr. Reed in his deposition, --</p> <p>11 A. Yeah.</p> <p>12 Q. -- that Xarelto can be ruled out as a</p> <p>13 confounding factor, do you have any basis to doubt</p> <p>14 that statement?</p> <p>15 A. Well I -- I mean we did -- we did the --</p> <p>16 the -- we --</p> <p>17 We talked about the reasons that a variable</p> <p>18 is -- is a confounder, --</p> <p>19 Q. Yeah.</p> <p>20 A. -- and as I've -- as I've said, the -- the</p> <p>21 reason for it being a confounder is that there is this</p> <p>22 association with the exposure and with the outcome,</p> <p>23 okay, and we've stipulated that that association may</p> <p>24 not be statistically significant.</p> <p>25 Q. We haven't stipulated, but you said that.</p>

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<p>1 A. Well -- and I've -- 2 In my report I referred to the work by -- 3 the -- the textbook by -- 4 Q. Breslow and Day. 5 A. -- Breslow and Day where they in fact show 6 example -- a counterexample of where that is in fact 7 true. 8 Q. That example related to cancer and age; 9 correct? 10 A. I've forgotten what the -- what the table 11 was, but -- 12 Q. Okay. 13 A. -- it -- it doesn't really -- it doesn't 14 really matter. It was just illustrating the -- the 15 point -- 16 Q. Okay. 17 A. -- that you could have -- you could have 18 associations that are not -- that don't achieve 19 statistical significance but they do in fact behave as 20 confounders in that they change the association when 21 you adjust for them. And it can go either way, it can 22 go -- make a very weak association stronger or it can 23 make a strong association go away. 24 Q. But you had said before that it's not always 25 necessary to control for a particular variable in the</p>	<p>1 MR. SACCHET: Okay. We'll get to the change 2 in relative risk in a minute, but first I'd like you 3 to, in just a moment, return -- turn your attention to 4 what will be marked as Exhibit -- 5 THE REPORTER: Twenty-six. 6 MR. SACCHET: -- 26. 7 (Exhibit 26 was marked for 8 identification.) 9 BY MR. SACCHET: 10 Q. Is this a document regarding reader 11 reactions to your article entitled "Confounding in 12 Epidemiologic Studies?" Which you can see on page 13 1309, the first page of actual text of the document, 14 on the title. First page of text after the title 15 page. 16 A. Oh, this is -- okay. 17 Q. Have you seen this document before? 18 A. Yes, I have. 19 Q. Okay. And you indeed published an article 20 called "Confounding in Epidemiologic Studies;" 21 correct, in 1989 -- 22 A. Yes. 23 Q. -- in Biometrics? 24 A. Nineteen -- 25 Well I think this is referring -- this</p>
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<p>1 event that it is not significantly related to the 2 outcome; correct? 3 A. You may need to control for it even if it is 4 not. 5 Q. The question was a little different. You've 6 said you do not need to control for a particular 7 variable in the event that there is not a significant 8 relationship between that variable and the outcome of 9 interest; correct? 10 A. No, I don't think that's quite what I -- 11 what I said. I -- the -- 12 When people are looking for confounders, 13 it's -- it's a tricky thing to look for it because 14 statistical significance is an easy thing for it to 15 sort of pop out, -- 16 Q. Uh-huh. 17 A. -- but a confounding variable is does the 18 control for this variable change the magnitude of the 19 association that you're looking for, -- 20 Q. Okay. 21 A. -- and so that's the relevant issue. 22 Q. We'll get -- we'll get there. 23 A. And that's -- and that's not what -- what -- 24 what Samet seemed to be talking about in his 25 deposition.</p>	<p>1 appeared in -- 2 Isn't this referring to the Wickramar -- 3 Wickramaratne -- 4 Q. Yes. 5 A. -- paper in '87? 6 Q. Okay. And you were a co-author of that 7 paper; correct? 8 A. Yes, I am. 9 Q. Okay. So as you can see on the first page 10 of text at 1309, Sander Greenland from the Department 11 of Epidemiology at UCLA -- 12 A. Yeah. 13 Q. -- provides a reader reaction; correct? 14 A. Yes. 15 Q. On page 1310, Paul Holland from Princeton, 16 New Jersey also provides a reader reaction; correct? 17 A. Yes. 18 Q. And on page 1317, Professor Mantel from 19 American University provides a review as well; 20 correct? 21 A. Yes. 22 Q. Professor Mantel is a notable statistician; 23 correct? 24 A. Yes, he is. Was. 25 Q. Oh. Okay. I didn't know that.</p>

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<p style="text-align: right;">Page 285</p> <p>1 And on page 1319 you provide a response.</p> <p>2 A. Yes.</p> <p>3 Q. And if you go to the paragraph on 1319</p> <p>4 beginning with "Mantel," do you see it says "Mantel</p> <p>5 raises...?"</p> <p>6 A. Yeah.</p> <p>7 Q. And it says, "Mantel raises the important</p> <p>8 question often facing the applied statistician of what</p> <p>9 to do when faced with the analysis or design of a</p> <p>10 particular study." Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. I'm going to skip the next sentence and then</p> <p>13 say, "Reasons given by Mantel for covariate adjustment</p> <p>14 are '...to reduce bias and to increase precision.'</p> <p>15 The particular example described by Mantel involves</p> <p>16 age as a potential confounder for cancer, a situation</p> <p>17 in which there is no question of whether there is in</p> <p>18 fact association. However, in other situations, one</p> <p>19 must decide whether to adjust on an empirical basis,</p> <p>20 and in these instances it was not always obvious how</p> <p>21 one should behave."</p> <p>22 That's what you wrote; correct?</p> <p>23 A. Yes.</p> <p>24 Q. You then say, "Statistical significance is</p> <p>25 not always the best guide as to which variables are</p>	<p style="text-align: right;">Page 287</p> <p>1 assoc -- I mean it's not -- it could --</p> <p>2 The reason it's not statistically</p> <p>3 significant could be that there is no association,</p> <p>4 okay, and that's in fact the criteria that -- that --</p> <p>5 that -- that's what's needed for there to be --</p> <p>6 Well, if there is no association, then it --</p> <p>7 then there is no confounding.</p> <p>8 Q. Okay.</p> <p>9 A. But there could be an association, it's just</p> <p>10 that that association -- you don't have enough power</p> <p>11 to -- to determine if that association -- for that</p> <p>12 association to be statistically significant.</p> <p>13 Q. Okay.</p> <p>14 A. And so in that case, you shouldn't make your</p> <p>15 choice based on the statistical significance but</p> <p>16 whether or not it actually does make a change in</p> <p>17 the -- in the effect.</p> <p>18 Q. Okay. And that's what you mean when you go</p> <p>19 on to say, "In this instance, the potential confounder</p> <p>20 was not significantly associated with disease, and yet</p> <p>21 the inference on the disease factor association was</p> <p>22 quite different depending on whether one controlled</p> <p>23 for the confounding variable in the analysis."</p> <p>24 A. Yes.</p> <p>25 Q. Correct?</p>
<p style="text-align: right;">Page 286</p> <p>1 confounders by any reasonable criterion, as was</p> <p>2 elegantly pointed out in an example given by Breslow</p> <p>3 and Day;" correct?</p> <p>4 A. Yes.</p> <p>5 Q. Why didn't you say it never is?</p> <p>6 A. Well it could be.</p> <p>7 Q. So in the event that there is not</p> <p>8 statistical significance between two variables, there</p> <p>9 may be no need to control as to whether that variable</p> <p>10 is a confounder?</p> <p>11 A. Well you could have an association that is</p> <p>12 not statistically significant but it is important to</p> <p>13 control because it -- because your estimate of</p> <p>14 association is biased if you don't control it.</p> <p>15 Q. But you may also have a situation in which</p> <p>16 the variable is non-significant to an outcome and you</p> <p>17 shouldn't control; correct?</p> <p>18 A. No. It -- it has nothing to -- it's --</p> <p>19 the --</p> <p>20 The point is -- the point I was making</p> <p>21 before is that -- is are -- is that statistical</p> <p>22 significance is not necessarily the criteria you</p> <p>23 should be looking at.</p> <p>24 Q. For confounding.</p> <p>25 A. For confounding. You could have</p>	<p style="text-align: right;">Page 288</p> <p>1 A. Uh-huh.</p> <p>2 Q. Okay. So the bottom line is whether or not</p> <p>3 something is significant, you should look at whether</p> <p>4 the odds ratio changes based on the uncontrolled</p> <p>5 calculation and the controlled calculation; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And in this instance you applied McGovern 10</p> <p>8 using the Jensen time periods and found that the odds</p> <p>9 ratio was 2.16; correct?</p> <p>10 A. Something like that.</p> <p>11 Q. Is that true?</p> <p>12 A. I'd have to look it up.</p> <p>13 Q. Page six.</p> <p>14 A. "In this case the results are" blah, blah,</p> <p>15 blah.</p> <p>16 2.168. I'm sorry. Okay.</p> <p>17 Q. Okay.</p> <p>18 A. Yeah.</p> <p>19 Q. So controlling for tinzaparin --</p> <p>20 A. Yeah.</p> <p>21 Q. -- in the Bair Hugger period compared to the</p> <p>22 Hot Dog period, based on Albrecht 10, yielded an odds</p> <p>23 ratio of 2.16; correct?</p> <p>24 A. That's right.</p> <p>25 Q. And the odds ratio that you calculated when</p>

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<p>1 you used Albrecht 10, based on the uncontrolled 2 calculation, was 2.76; correct? 3 A. That's correct. 4 Q. The decrease in the odds ratio is .6; 5 correct? 6 A. That's right. 7 Q. So that would be at best the magnitude of 8 the degree of confounding if there is any confounding, 9 correct, based on your calculation? 10 A. Yeah. Well that -- that -- that change 11 would be a change due to controlling for -- 12 controlling for use -- use of this -- of -- of this -- 13 of this treatment, whatever that corresponds to. 14 Q. But I want to be clear that the change is .6 15 in the odds ratio; correct? 16 A. That's right. That's right. 17 Q. In your response to Mantel you say that the 18 inference on the disease factor association was quite 19 different when one controlled for age with respect to 20 cancer; correct? 21 A. It depended -- 22 I don't know what the example was here. 23 Q. Okay. Would you -- 24 A. Whatever it is. 25 Q. -- view a change of .6 to be quite</p>	<p>1 Q. This odds -- this odds ratio is still above 2 2.0 -- 3 A. It is. 4 Q. -- when controlling for the 5 thromboprophylaxis; correct? 6 A. That's right. 7 Q. There is still a doubling of the risk even 8 when controlling for the thromboprophylaxis; correct? 9 A. That's right. So -- 10 Q. Okay. 11 A. -- if you -- 12 You're looking at a difference at -- at the 13 change above one, -- 14 Q. Okay. 15 A. -- not -- not zero. 16 Q. But you would still agree that the -- 17 A. It's a fairly big chart -- change. 18 Q. -- the change -- 19 The controlled thromboprophylaxis OR is 20 still above 2.0. 21 A. It is, yes. 22 Q. And it -- 23 That means it's still a doubling of the risk 24 even when the thrombo -- 25 A. But the point -- the point estimate is</p>
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<p>1 different? 2 A. I'd say it's a fair -- fair difference, yes. 3 Q. Okay. 4 A. So 2. -- 2.76, yeah, I mean that's -- 5 it's -- 6 Q. Approximately 20 percent. 7 A. Oh, it's more than 26 percent; isn't it? 8 It's -- 9 Q. I don't think so. 10 A. -- two -- 11 Q. .6 -- 12 A. -- point -- 13 Q. -- on 2.76? 14 A. Well the 2.76, that's a -- an increase of 15 1.76. 16 Q. From 2.76 to 2.16 is a difference of .6. 17 A. Right. 18 Q. Okay. 19 A. And so if there's no association, the odds 20 ratio is -- is -- is one. 21 Q. You're getting that from controlling both -- 22 A. If there's no -- no association, you're 23 looking at -- 24 Q. Correct. 25 A. -- the ratio of two incidence rates.</p>	<p>1 above. I mean look at the confidence limits. 2 Q. Of your calculation? 3 A. .7 -- 4 After you control for it. 5 Q. Yes. 6 A. .73 to 8. -- 7 I mean it's still -- 8 Q. It's -- 9 A. The estimate of what the effect is is not 10 very precise I would say. 11 Q. It's a third of the size of your Jensen 12 reanalysis; is it not? Your Jensen reanalysis has as 13 25-point confidence interval. 14 A. The 25, that's -- 15 Q. One to 25. 16 MR. GORDON: Object to the form of the 17 question, assumes facts not in evidence. 18 A. Yeah. I -- you're looking at -- 19 I mean those are not a fair comparison. I 20 mean -- 21 Q. Why not? 22 A. I mean both of them are very poor estimates. 23 Q. Yours is three times the size -- 24 A. Well you're looking at the range. 25 Q. -- of this.</p>

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<p style="text-align: right;">Page 293</p> <p>1 A. Remember, I said, you know, the -- when you 2 construct a confidence interval on an odds ratio, you 3 generally do it on the log transformation, -- 4 Q. Okay. 5 A. -- and so once you threw it -- do it in the 6 log, you have to look at it in the log scale. 7 Q. Okay. You would agree, nonetheless, that 8 the odds -- that the confidence interval you 9 calculated based on the Jensen reanalysis is larger 10 than the confidence interval of both the McGovern 11 study and the confidence interval that you report when 12 controlling for the thromboprophylaxis. 13 A. The range of the two would be greater, yes, 14 the range of the two would be greater, but a big part 15 of that reason for the change in the range, the 16 arithmetic difference in that range, is because the 17 odds ration is much smaller. In the other example in 18 the -- in the -- from the -- from the Jensen 19 comparison, the odds ratio was 4.77. 20 Q. Okay. 21 A. So that's more than twice -- 22 Q. Okay. 23 A. -- what the odds ratio is here. 24 Q. Your odds ratio is more than three times the 25 ev -- the confidence interval here. Your confidence</p>	<p style="text-align: right;">Page 295</p> <p>1 A. No. 2 Q. So you haven't reviewed any published 3 literature regarding the safety of Xarelto with 4 respect to deep joint infection. 5 MR. GORDON: Objection, asked and answered. 6 A. No, I've -- 7 Q. Are you going to publish it? 8 A. No. 9 Q. So there is no published literature that you 10 are aware of that suggests a relationship between the 11 variable of a thromboprophylaxis on the outcome of 12 deep joint infection. 13 A. I don't know of any. 14 Q. Okay. If we could, let me show you another 15 document. 16 A. I mean it is interesting that they in 17 fact -- they seem to have not -- 18 They went -- they went back to using the -- 19 using the treatment they were originally using even 20 though the Jensen paper did not find it statistically 21 significant. 22 Q. You don't have an ex -- expertise in 23 infectious disease; do you? 24 A. No. 25 Q. You're not a medical doctor.</p>
<p style="text-align: right;">Page 294</p> <p>1 interval is three times the size of the confidence 2 interval even though the odds ratio here is half the 3 amount of the odds ratio you reported -- 4 A. Yes. Okay. 5 Q. -- in the Jensen reanalysis. 6 A. Okay. 7 Q. Okay. 8 A. So I don't -- I don't -- I don't understand 9 what your point is. But -- 10 Q. My point is that it's clear that the Jensen 11 reanalysis has more variability than does your 12 calculation of the 2.16 odds ratio -- 13 A. The difference between the high and low -- 14 Q. -- when controlling for the 15 thromboprophylaxis; correct? 16 A. The difference be -- the -- the -- 17 The difference between the high and the low 18 of the confidence interval is greater on that one 19 than -- is -- is diff -- quite different between those 20 two. I agree to that. 21 Q. It's greater. 22 A. It's greater. I agree with that. 23 Q. Thank you. 24 As to the Jensen reanalysis, have you 25 published your reanalysis of the Jensen study?</p>	<p style="text-align: right;">Page 296</p> <p>1 A. I'm not. 2 Q. You don't know why they changed back to 3 tinzaparin. 4 A. No, I -- no, I don't. I don't know if this 5 is the basis of it or not. 6 Q. Okay. 7 A. But I mean this was the ba -- 8 It was Jensen's paper that -- that McGovern 9 is quoting, right, -- 10 Q. Uh-huh. 11 A. -- as the -- as for saying why it's not a 12 confounder? 13 Q. And the Jensen -- 14 A. And while the Jensen paper is not -- not 15 statistically significant, -- 16 Q. Uh-huh. 17 A. -- they nevertheless changed the policy -- 18 changed the regimen that they were using at Wansbeck. 19 Q. Okay. But you don't know why they did. 20 A. No, I don't. 21 Q. Okay. 22 A. I find it interesting. 23 Q. Did you ask anyone why they changed from 24 tinzaparin to Xarelto and back to tinzaparin? 25 A. No.</p>

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<p>1 (Exhibit 27 was marked for 2 identification.) 3 BY MR. SACCHET: 4 Q. Did you ask 3M to investigate the issue? 5 A. Of why they changed back? 6 Q. Yes. 7 A. No. 8 Q. Okay. This is a section from Breslow and 9 Day; correct? 10 A. Is it? I don't -- I don't know. It 11 doesn't -- 12 Oh, okay. Seems to be. 13 Q. And here on page 105 Breslow and Day state, 14 about in the middle of the page, paragraph begins "A 15 third way..." Do you see that? 16 A. Uh-huh. 17 Q. And the third sentence says, "Stratification 18 by factors which are not genuine confounding variables 19 would therefore increase the variability of the 20 estimates without eliminating any bias..." Do you 21 agree with that statement? 22 A. Trying to see what they're talking about 23 here. 24 MR. GORDON: I'm sorry, where are you? 25 MR. SACCHET: I'm on page 105 and the</p>	<p>1 A. So we're talking about vari -- variance and 2 not bias. Okay. 3 Q. Okay. So in the event that, for the sake of 4 argument, the thromboprophylaxis is not in fact 5 related to the outcome of interest, which is deep 6 joint infection, if one were to control for the 7 thromboprophylaxis, that would inject variance; 8 correct? 9 MR. GORDON: Object to the form of the 10 question, assumes facts not in evidence, incomplete 11 hypothetical. 12 A. I mean I think what you see -- what -- 13 What this is saying, if it's not, then they 14 would -- it would have no effect on the estimate but 15 it would increase the variance. 16 Q. Okay. 17 A. Okay? 18 Q. Yeah. 19 A. In the control that -- that I did in this 20 analysis, the estimate did change. 21 Q. And the confidence interval did, too; 22 correct? 23 A. And confidence -- 24 They both changed, yes. 25 Q. And that confidence interval measures</p>
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<p>1 paragraph starting "A third way...", in the third 2 par -- in the third sentence. 3 A. Okay. They're talking about overmatching. 4 Okay. 5 Q. Yes. Okay. And then they say, "It is 6 commonly seen when data are stratified by a variable 7 known to be associated with exposure but not in itself 8 independently related to disease;" correct? 9 A. Yes. 10 Q. So to the extent that you have a factor and 11 you control for that factor, even though it's related 12 to the -- even though it's related to the treatment 13 but not necessarily the outcome, that will result in 14 unnecessary bias; correct? 15 MR. GORDON: Object to the form of the 16 question. 17 A. I don't think the term they're using is 18 "bias," I think they're talking about variability. 19 Q. Okay. So -- 20 A. That's different. 21 Q. Okay. You would agree to the extent that my 22 question involves variance or variability as opposed 23 to bias. 24 A. Okay. 25 Q. Okay.</p>	<p>1 variance. 2 A. That's -- that's an indication of precision. 3 Q. Okay. 4 A. Yeah. 5 Q. If we look at -- 6 A. And so what they're saying here is that 7 you've -- you've got a variable, there's no point in 8 controlling it. To control for bias, it's not going 9 to do anything to that, -- 10 Q. Okay. 11 A. -- and so you're just throwing it in there 12 unnecessarily and that's going to increase the 13 variance. 14 Q. Okay. 15 A. And so -- so I would -- I would agree with 16 that, but I would disagree that that corresponds to 17 that particular analysis on page six -- 18 Q. In -- 19 A. -- of my report. 20 Q. -- the bottom paragraph, the last full 21 sentence states, "Good evidence may be available from 22 previous studies that C is not causally related to 23 disease, in which case it should not be incorporated 24 as a confounder." Do you see that? 25 A. Yes.</p>

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<p>1 Q. Are you aware that the record studies found</p> <p>2 that Xarelto is not related to infection?</p> <p>3 MR. GORDON: Objection, asked and answered,</p> <p>4 lack of foundation.</p> <p>5 A. I think I said I had not looked at the</p> <p>6 record studies.</p> <p>7 Q. Would it be helpful to look at one?</p> <p>8 A. I mean I -- it --</p> <p>9 When I was looking within the Albright 10</p> <p>10 data set, I found the association that I reported.</p> <p>11 Now I think the premise of your question is: Is the</p> <p>12 association that I found, is that a causal association</p> <p>13 or not? The way this study was designed, is this</p> <p>14 temporal? You know, these time periods are changing.</p> <p>15 And as I show in Fig. 2 --</p> <p>16 Q. Okay.</p> <p>17 A. -- show in Fig. 2 and I present the --</p> <p>18 related to that I show in figure -- I'm sorry, on</p> <p>19 page -- ah, where is that? On page four, the last</p> <p>20 paragraph, it compares the infection rates by</p> <p>21 quarter --</p> <p>22 Q. Yeah.</p> <p>23 A. -- and we got a chi-square of 15.5 on six</p> <p>24 degrees of freedom, p-value of .0167. So what that</p> <p>25 suggests is that the incidence rates during the Bair</p>	<p>1 what, two and a half times as much variability as what</p> <p>2 I would expect to see if the only variation that was</p> <p>3 taking place was just a random fluctuation based on,</p> <p>4 you know, what's going on with the use of -- of -- of</p> <p>5 these surgical procedures at Wansbeck.</p> <p>6 Q. You didn't do that calculation with respect</p> <p>7 to the reanalysis of the Jensen data; correct?</p> <p>8 A. I -- I didn't -- I didn't allow for random</p> <p>9 variability other than the binomial variability --</p> <p>10 Q. Okay.</p> <p>11 A. -- that -- that we assumed. No, I -- I took</p> <p>12 that at a face value. And -- and it could be random.</p> <p>13 My assumption is it's not random. My assumption is</p> <p>14 it's due to other factors that are -- that were</p> <p>15 affecting risk at Wansbeck during this time period.</p> <p>16 Q. That's an assumption.</p> <p>17 A. It is.</p> <p>18 Q. Okay. I want to go back to the -- what we</p> <p>19 were talking about with respect --</p> <p>20 Did you do any investigation to determine</p> <p>21 whether your assumption was correct or not?</p> <p>22 A. I -- I have no further --</p> <p>23 I have not been in contact with Wansbeck or</p> <p>24 anyone else involved with this to know that for</p> <p>25 certain. I guess a part of my -- my -- my reasons for</p>
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<p>1 Hugger period were changing quite a lot, and those</p> <p>2 differences were statistically significant.</p> <p>3 Q. Okay.</p> <p>4 A. So this is not a period where things were</p> <p>5 just under well controlled.</p> <p>6 Q. Are you aware of whether deep joint</p> <p>7 infections are always constant or whether there is</p> <p>8 variability in deep joint infections more generally?</p> <p>9 A. Well if there is variability more generally,</p> <p>10 then that needs to be taken into account in the</p> <p>11 analysis, and this analysis does not do that.</p> <p>12 Q. When you conducted --</p> <p>13 A. I did not do that, and McGovern certainly</p> <p>14 didn't do it either.</p> <p>15 Q. When you construct a statistical model, the</p> <p>16 confidence interval accounts for the variance of the</p> <p>17 data; correct?</p> <p>18 A. Well it should. But the confidence</p> <p>19 intervals that I computed and the confidence intervals</p> <p>20 that McGovern computed don't take that -- that</p> <p>21 variability into account.</p> <p>22 Q. Okay.</p> <p>23 A. The expected value of this chi-square</p> <p>24 statistic is equal to the degrees of freedom, so you</p> <p>25 expect it to be six, in fact it's 15.5, so there's,</p>	<p>1 thinking there were other things going on is the</p> <p>2 Gillson paper, for example, enumerates such a huge</p> <p>3 array of things that were taking place at -- what is</p> <p>4 it -- Northumbria group of hospitals, --</p> <p>5 Q. Okay.</p> <p>6 A. -- so they were having a problem.</p> <p>7 Obviously, NHS was -- was calling them on having a</p> <p>8 high infection rate that they needed to do something</p> <p>9 about, and the -- the Gissell paper elaborates on all</p> <p>10 the things that they were trying to do to bring this</p> <p>11 thing under control, and there were a lot of other</p> <p>12 things other than switching to Hot Dog.</p> <p>13 Q. Okay. Did you ask 3M for any info with</p> <p>14 respect to this issue?</p> <p>15 A. No.</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 Q. Okay. Are you aware that in the Gillson</p> <p>19 article the descriptor for infection is SSI?</p> <p>20 MR. GORDON: Object to the form of the</p> <p>21 question.</p> <p>22 Q. The title of the article is SSI.</p> <p>23 A. Which paper are you talking about?</p> <p>24 Q. You just referenced the Gillson article, --</p> <p>25 A. Gillson, okay.</p>

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<p>1 Q. -- "Implementing Effective SSI Measures." 2 A. Right. Yes. 3 Q. Do you know what "SSI" stands for? 4 A. Ahh, oh -- 5 I've forgotten. 6 Q. Surgical-site infection ring a bell? 7 A. Surgical-site infection. Exactly, yeah. 8 Q. Surgical-site infections are not the same 9 thing as deep joint infections. 10 MR. GORDON: Object to the form of the 11 question, lack of foundation, misconstrues the 12 evidence and assumes facts not in evidence. 13 Q. Do you know whether an SSI is the same as a 14 DJI? 15 MR. GORDON: Same objection. 16 A. It's -- it's not the same, it's not the same 17 thing. They are -- they would be -- 18 Are you saying -- suggesting they are not 19 related? 20 Q. I'm suggesting that -- 21 Do you know whether the measures that were 22 implemented in the Northumbria trust were specific to 23 SSI or DJI? 24 A. I think -- 25 Well the paper is entitled for SSI.</p>	<p>1 But I -- I believe that they would be 2 related to each other. And things that you're doing 3 to control SSI, my understanding is you would have -- 4 you would have effects on -- on PJI as well. 5 Q. What's your understanding based on? 6 A. Well looking at -- well I mean the -- one -- 7 This is from the -- from the Gillson paper. 8 Q. What is? 9 A. A patient with a -- with a -- with surgery 10 on his knee. 11 Q. Do you see the implant? 12 A. I see the surgery on his knee. 13 Q. Do you know whether that would result in 14 either a superficial wound infection on the skin or 15 whether it would result in a deep infection on a 16 prosthetic? 17 A. I don't know. If it was a deep infection, I 18 think that would be something they would -- they would 19 be interested in. 20 You don't think that -- you don't think they 21 would be interested in that as -- as respect to the 22 surgery? 23 Q. Are you asking me? 24 A. Yeah. 25 Q. I'm --</p>
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<p>1 Q. So you don't know whether they were specific 2 to deep joint infection. 3 A. Well I would assume that they would -- they 4 would be effective on affecting both. I mean 5 orthopedic surgery appears to be one of the things 6 that they are in fact looking at. 7 Q. Can you define SSI? 8 A. I don't know the -- 9 I don't know. I'm -- it's not a -- an area 10 that I've particularly done -- done work -- work on. 11 I -- 12 Q. Can you define DJI? 13 A. It's -- it's again the -- 14 It's joint -- joint infections -- 15 Q. Okay. 16 A. -- that -- that you're looking at. 17 Q. But you have no scientific basis or 18 expertise to conclude whether or not the inter -- 19 interventions that are mentioned in the Gillson 20 article which relate to SSI would have an impact on 21 deep joint infection; correct? 22 A. It's -- 23 They're not areas that I have -- that I 24 have -- that I have personally done research on. 25 My -- my --</p>	<p>1 A. I mean you -- you seem to be suggesting that 2 there's no effect. Why -- why what you're asking 3 me -- 4 Q. I would let -- 5 Your -- your report concludes that the SSI 6 bundle may have had an effect on deep joint infection 7 rates; correct? 8 A. Yes. The things that they were doing to 9 control SSI may have had an effect. 10 Q. You have no scientific basis to make that 11 conclusion. 12 A. I'm -- no, no. I'm just -- just assuming 13 that it does. 14 Q. Thank you. 15 Do you know if any articles that you're 16 relying on relate to SSI versus DJI? 17 A. No. 18 Q. So you're not sure whether the publications 19 that you've cited on page 14 of your report are 20 specific to deep joint infection or a surgical-site 21 infection. 22 A. Oh. Some of them -- 23 I'm not sure which articles you're -- you're 24 talking about. 25 Q. Well do you know offhand? I don't want to</p>

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<p style="text-align: right;">Page 309</p> <p>1 spend a ton of time on this.</p> <p>2 A. I don't -- I don't know offhand.</p> <p>3 Q. Okay.</p> <p>4 A. I --</p> <p>5 Q. With respect to the conclusions that you've</p> <p>6 offered in your report, did you distinguish between</p> <p>7 SSI and DJI?</p> <p>8 A. I don't know that you're --</p> <p>9 Most of what I was talking about in the</p> <p>10 report has to do with analysis of -- of -- of</p> <p>11 McGovern.</p> <p>12 Q. Do you know whether Albrecht 10, for</p> <p>13 example, contained data on SSI versus DJI?</p> <p>14 A. I don't recall that it -- it did. I think</p> <p>15 it was basically looking at the -- the internal</p> <p>16 infections.</p> <p>17 Q. But you don't know whether those infections</p> <p>18 were SSI or DJI.</p> <p>19 A. I --</p> <p>20 MR. GORDON: Object to the form of the</p> <p>21 question.</p> <p>22 A. I wasn't --</p> <p>23 They were looking at in -- in -- whatever</p> <p>24 their definition was of -- of infection.</p> <p>25 Q. But you don't know what that is.</p>	<p style="text-align: right;">Page 311</p> <p>1 columns. They are -- they are labeled, and somewhere</p> <p>2 in here --</p> <p>3 I've forgotten the variable names that they</p> <p>4 used.</p> <p>5 Q. Do you see it?</p> <p>6 A. Deep infection.</p> <p>7 Q. Do you know whether that's DJI or SSI?</p> <p>8 A. I don't know.</p> <p>9 Q. Okay. Do you know whether --</p> <p>10 A. Well DJ -- I think it's DJ -- DJI, that DJI</p> <p>11 is deep joint infection.</p> <p>12 Q. Do you know whether the mechanism of</p> <p>13 infection differs between the DJI and SSI?</p> <p>14 A. No.</p> <p>15 Q. Okay. I'd like to turn back to the Breslow</p> <p>16 and Day article that we were looking at, which has</p> <p>17 been marked as Exhibit 26 I believe.</p> <p>18 THE REPORTER: Before we do that, let's go</p> <p>19 off the record, take five minutes.</p> <p>20 (Recess taken.)</p> <p>21 BY MR. SACCHET:</p> <p>22 Q. Professor Holford, you have also analyzed</p> <p>23 the change in the antibiotic regime that occurred</p> <p>24 during the McGovern study; correct?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 310</p> <p>1 A. They de --</p> <p>2 I don't re -- recall exactly what the detail</p> <p>3 is there. They defined it in -- it's defined in</p> <p>4 McGovern, and it's identified as one of the variables</p> <p>5 that is in Albrecht -- Albrecht 10.</p> <p>6 Q. Albrecht 10 says what they're defined as,</p> <p>7 whether they are DJI or SSI?</p> <p>8 A. I don't recall if it said that. It just</p> <p>9 said a --</p> <p>10 Q. I'll represent to you that it doesn't.</p> <p>11 A. Okay.</p> <p>12 Q. So you're not sure one way or the other</p> <p>13 whether the data in Albrecht Exhibit 10 is specific to</p> <p>14 SSI versus DJI, considering that the Gillson article</p> <p>15 is talking about SSI.</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence.</p> <p>18 A. I was using the definition that -- that was</p> <p>19 in Albrecht 10.</p> <p>20 Q. Where is the definition in Albrecht 10?</p> <p>21 A. Well they defined it to -- to define their</p> <p>22 variable that indicated --</p> <p>23 What was the variable called?</p> <p>24 Q. It's not in there; is it, professor?</p> <p>25 A. Well there's one of the -- it's one of these</p>	<p style="text-align: right;">Page 312</p> <p>1 Q. And there was a change from Gentamicin to</p> <p>2 Gentamicin plus Teicoplanin; correct?</p> <p>3 A. That's correct.</p> <p>4 Q. And the change happened at the tail end of</p> <p>5 the Bair Hugger period with some time left, and then</p> <p>6 it was fully in force during the Hot Dog period;</p> <p>7 correct?</p> <p>8 A. Yeah.</p> <p>9 MR. GORDON: Well I'll object to the form of</p> <p>10 the question.</p> <p>11 Q. Are you aware of the relationship between</p> <p>12 using prophylactic antibiotics on DJI versus SSI?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question, lack of foundation.</p> <p>15 A. I'm not familiar with that, no.</p> <p>16 Q. Did you conduct any research to determine</p> <p>17 how antibiotics operate as to the outcome of DJI</p> <p>18 versus SSI?</p> <p>19 A. No.</p> <p>20 Q. Did you ask 3M for any information about how</p> <p>21 change from Gentamicin to Gentamicin plus Teicoplanin</p> <p>22 might affect deep joint infection rates?</p> <p>23 A. No.</p> <p>24 Q. Do you have any knowledge of how Gentamicin</p> <p>25 versus Gentamicin and Teicoplanin affects joint</p>

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<p style="text-align: right;">Page 313</p> <p>1 infection rates?</p> <p>2 A. Other than the -- the analysis that I did</p> <p>3 using Albrecht 10, that -- that's basically what I was</p> <p>4 using.</p> <p>5 Q. In your report you assume that the</p> <p>6 thromboprophylaxis may be a confounding factor, but</p> <p>7 you never state as much with respect to the</p> <p>8 antibiotic; is that true?</p> <p>9 A. I don't know if I stated it. It is -- it is</p> <p>10 potentially a -- a -- a confounding variable and in</p> <p>11 fact I did adjust for it in -- I did present an</p> <p>12 analysis where I adjusted for it.</p> <p>13 Q. So did you adjust for the antibiotic without</p> <p>14 considering whether it was a confounding factor?</p> <p>15 A. Well, I mean whether it's a confounding</p> <p>16 factor, as I -- as I said before, it -- it depends on</p> <p>17 whether -- whether there is a change in the --</p> <p>18 It affects the -- the association.</p> <p>19 Q. Okay.</p> <p>20 A. And in this case the association -- let's</p> <p>21 see.</p> <p>22 When we just controlled for the</p> <p>23 thromboprophylaxis --</p> <p>24 Q. I think we're on the antibiotic.</p> <p>25 A. Yes. When we just controlled for -- for</p>	<p style="text-align: right;">Page 315</p> <p>1 MR. GORDON: On page six.</p> <p>2 Q. It's on page six.</p> <p>3 A. Oh, I'm sorry.</p> <p>4 Q. Right under the heading "Comparison of the</p> <p>5 effect of antibiotic regimen on study results." And</p> <p>6 you report that there was a rate of infection during</p> <p>7 the Bair Hugger period when Gentamicin was used of</p> <p>8 1.92 percent; correct?</p> <p>9 A. Oh, okay. This is --</p> <p>10 Yeah. We were -- I think we were talking</p> <p>11 about two different things. This is, I think, just</p> <p>12 looking at the effect of an antibiotic on --</p> <p>13 Q. Yes.</p> <p>14 A. Yeah.</p> <p>15 Q. Okay.</p> <p>16 A. I was talking about controlling for it.</p> <p>17 Yeah.</p> <p>18 Q. Okay. So here we essentially controlled for</p> <p>19 the use of the Bair Hugger and viewed infection rates</p> <p>20 when Gentamicin was applied versus when Gentamicin</p> <p>21 plus Teicoplanin was applied; correct?</p> <p>22 A. That's right. Because it's only during</p> <p>23 the --</p> <p>24 Q. Yeah.</p> <p>25 A. -- Bair Hugger.</p>
<p style="text-align: right;">Page 314</p> <p>1 the -- for the thromboprophylaxis, the -- the odds</p> <p>2 ratio was, what, 2.49? Is that right? No, I'm sorry,</p> <p>3 2.16.</p> <p>4 Q. That's the odds ratio for controlling for</p> <p>5 the thromboprophylaxis; correct?</p> <p>6 A. From -- from --</p> <p>7 Yes, right.</p> <p>8 Q. And we're talking about the antibiotic.</p> <p>9 A. And then so now when we add, in addition to</p> <p>10 controlling for the thromboprophylaxis we're adding</p> <p>11 the antibiotic, which is what you were asking about --</p> <p>12 Q. Well I actually wasn't asking about that.</p> <p>13 I'm asking for just with respect to the antibiotic,</p> <p>14 not controlling for both, just controlling for the</p> <p>15 antibiotic. You did that calculation prior to the</p> <p>16 double control; correct?</p> <p>17 A. I don't know that I did the single control.</p> <p>18 Q. Okay.</p> <p>19 A. I looked -- I looked --</p> <p>20 I did a double control.</p> <p>21 Q. You don't recall doing a single control on</p> <p>22 the antibiotic?</p> <p>23 A. I don't think I did.</p> <p>24 Q. Well you did.</p> <p>25 A. Oh, I did? Okay.</p>	<p style="text-align: right;">Page 316</p> <p>1 Q. Yeah.</p> <p>2 A. Sure.</p> <p>3 Q. And protocol one, which we'll call the</p> <p>4 Gentamicin administration, resulted in an infection</p> <p>5 rate of 1.92 percent in patients; correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And then protocol two, when</p> <p>8 Gentamicin plus Teicoplanin was used, the rate went up</p> <p>9 to 3.13; correct?</p> <p>10 A. That's right.</p> <p>11 Q. That's an increase in the infection rate;</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And that's the combination of antibiotics</p> <p>15 that was used during the Hot Dog period; correct?</p> <p>16 A. Yes.</p> <p>17 Q. So actually, the combination of antibiotics</p> <p>18 that was used resulted in a higher infection rate</p> <p>19 between -- compared to the drug that was used with</p> <p>20 just Bair Hugger patients; correct?</p> <p>21 A. That's right.</p> <p>22 Q. So if anything --</p> <p>23 A. Yeah. It's the com -- wait.</p> <p>24 That's right. Yeah.</p> <p>25 Q. Okay.</p>

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<p>1 A. The switchover. Okay. Sorry.</p> <p>2 Q. So if anything, there's actually reverse</p> <p>3 confounding in the direction that the use of</p> <p>4 Gentamicin plus Teicoplanin was less effective than</p> <p>5 the use of just Gentamicin; correct?</p> <p>6 A. It appears to be, yes.</p> <p>7 Q. So based on that conclusion, the odds ratio</p> <p>8 as reported in the McGovern study could even be higher</p> <p>9 in the event that we controlled for the use of</p> <p>10 Gentamicin plus Teicoplanin; correct?</p> <p>11 A. Well --</p> <p>12 Q. You just told me statistical significance</p> <p>13 did not matter.</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question, misstates his testimony.</p> <p>16 A. I mean the issue of it being a confounder is</p> <p>17 does it affect the association -- does it affect the</p> <p>18 measure of association between -- the --</p> <p>19 Well, in this case we're looking at Bair</p> <p>20 Hugger, Bair Hugger/Hot Dog, does it -- does it affect</p> <p>21 that association.</p> <p>22 Q. You didn't report an association; did you?</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question.</p> <p>25 A. Yeah, it --</p>	<p>1 that Gentamicin may be less effective than Gentamicin</p> <p>2 plus Teicoplanin; correct?</p> <p>3 A. It -- it --</p> <p>4 The point estimates go in that direction.</p> <p>5 It's not --</p> <p>6 Q. Okay.</p> <p>7 A. -- statistically significant, --</p> <p>8 Q. Okay.</p> <p>9 A. -- although it's --</p> <p>10 It's sort of unclear as to whether or not it</p> <p>11 does.</p> <p>12 Q. With respect to confounding, you previously</p> <p>13 stated that statistical significance is not</p> <p>14 determinant of whether there is confounding; correct?</p> <p>15 A. That's right.</p> <p>16 Q. So whether or not the p-value is .1683 does</p> <p>17 not mean that there was reverse confounding with</p> <p>18 respect to the odds ratio reported in the McGovern</p> <p>19 study; correct?</p> <p>20 A. It's -- it --</p> <p>21 Well it basically means that it's -- it's --</p> <p>22 it's -- it could go either way.</p> <p>23 Q. It could --</p> <p>24 A. It's not -- it's not clear.</p> <p>25 Q. Okay. And you have not reported an odds</p>
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<p>1 Q. Did you report an association with respect</p> <p>2 to controlling for the antibiotic in the Bair Hugger</p> <p>3 arm of the study?</p> <p>4 MR. GORDON: Just the antibiotic?</p> <p>5 MR. SACCHET: Yeah.</p> <p>6 A. Not just the antibiotic, no. That's what I</p> <p>7 said, I didn't do that.</p> <p>8 Q. You didn't do that.</p> <p>9 A. Look at the effect of --</p> <p>10 Well I -- I looked at the effect of -- of</p> <p>11 the antibiotic --</p> <p>12 Q. Yeah.</p> <p>13 A. -- on risk of infection, --</p> <p>14 Q. Okay.</p> <p>15 A. -- and that was this difference of, oh, 1.9</p> <p>16 versus 3.1 infection rate with a p-value of .17.</p> <p>17 Q. Okay. And the percent of infection when</p> <p>18 using Gentamicin plus Teicoplanin went up compared to</p> <p>19 the use of just Gentamicin; correct?</p> <p>20 A. That's right.</p> <p>21 Q. And in the McGovern study, all the Hot Dog</p> <p>22 patients received Gentamicin plus Teicoplanin;</p> <p>23 correct?</p> <p>24 A. Yeah.</p> <p>25 Q. This calculation that you performed shows</p>	<p>1 ratio with respect to that calculation; correct?</p> <p>2 A. No, it does --</p> <p>3 No, I have not.</p> <p>4 Q. So in order to determine whether there was</p> <p>5 reverse confounding or general confounding, you have</p> <p>6 not made the calculation in order to make that</p> <p>7 conclusion; correct?</p> <p>8 A. I haven't said whether or not it's reverse</p> <p>9 or --</p> <p>10 I'm not -- I'm not sure what -- what you</p> <p>11 mean by "reverse" or --</p> <p>12 Q. That's what I said, "whether or not." You</p> <p>13 don't know whether there was confounding because you</p> <p>14 haven't reported an odds risk ratio with respect to</p> <p>15 just the control for the antibiotic; correct?</p> <p>16 A. Well it's not just control. I've -- I've</p> <p>17 controlled for both antibiotic and thrombo.</p> <p>18 Q. I understand. But with respect to</p> <p>19 controlling for the antibiotic in this calculation --</p> <p>20 A. Yes.</p> <p>21 Q. -- you report infection rates and you report</p> <p>22 a p-value, you do not report an odds ratio; correct?</p> <p>23 A. That's correct.</p> <p>24 Q. There is no way to determine whether the</p> <p>25 odds ratio increased compared to what was provided in</p>

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<p>1 the McGovern study or whether it decreased, 2 correct, -- 3 A. Which odds -- 4 Q. -- when com -- 5 A. -- ratio are you talking about? 6 Q. Either the 3.8 or the 2.76 that you 7 calculated based on Albrecht 10. You have no basis to 8 compare those odds ratios to this calculation. 9 A. Well I compared the odds -- I mean I 10 didn't -- 11 I don't report the odds ratio, but you can 12 pretty good -- get a pretty good idea of what -- about 13 what it's going to be -- 14 Q. You told me -- 15 A. -- because the infection rate -- let's see. 16 "In order to control for the...one must use 17 the Bair Hugger period that -- that shares the 18 antibiotic and thromboprophylaxis regimen used in the 19 Hot Dog period," so -- which had an infection rate of 20 three out of 270, 1.1 percent, and compare that with 21 four out of 372, which is 1.08 percent. 22 Q. You're looking at controlling for both 23 variables, correct, right now? 24 A. That is correct. 25 Q. I want to go back to when you just</p>	<p>1 Q. Yeah. And you haven't done -- 2 A. So whether or not it's associated with -- 3 Well in this study it -- it certainly is 4 associated with -- with whether or not the Bair Hugger 5 or the Hot Dog was used. In general, who knows? 6 Q. You don't know whether -- 7 A. Well -- 8 Q. -- the Gentamic -- 9 A. -- it depends on what -- what -- what is 10 done by the institution. 11 Q. You don't know whether Gentamicin is more or 12 less effective than Gentamicin plus Teicoplanin -- 13 A. Well that's a different question. 14 Q. -- in terms of deep joint infection. That's 15 the question right now. Do you know? 16 A. Well there is the -- 17 The analysis based on these data -- 18 Q. That shows -- 19 A. -- found -- found the -- the result was not 20 statistically significant, the difference of 2.19 21 percent versus 3.1, but -- but -- 22 Q. And the infection rate went up with 23 Gentamicin plus Teicoplanin. 24 A. That's right. 25 Q. Okay.</p>
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<p>1 controlled for the antibiotic, which is what we're 2 talking about. You did not provide an odds ratio. 3 A. I did not -- 4 That's right, I didn't provide it. 5 Q. You did not determine how or whether the 6 antibiotic by itself is a confounding variable. 7 A. By -- by itself, no. By itself, no. 8 Q. And you have -- 9 A. But I've controlled for both of them -- 10 Q. We'll get there. I'm just talking about 11 this calculation. 12 You do not know the degree of confounding, 13 if any, caused by only the antibiotic. 14 A. That's right. I didn't do that. 15 Q. And you have not reviewed any literature to 16 suggest that an antibiotic is a confounding factor on 17 deep joint infections. 18 MR. GORDON: Object to the form of the 19 question. 20 A. I don't see -- understand that -- understand 21 your -- your question. To be a confounding variable, 22 as we've said, it has to be associated with -- with 23 the -- with the outcome -- 24 Q. Okay. 25 A. -- and the variable you're looking at.</p>	<p>1 A. The one -- the one is higher. It's not -- 2 That difference is not statistically 3 significant. 4 Q. Okay. Based on that -- 5 A. When I -- when I added that into the 6 analysis and controlled for that after I had already 7 controlled from thromboprophylaxis, the -- any 8 association that -- an association that was 2.1 -- 9 six was it? -- com -- disappeared effectively 10 completely, I mean 1 -- 1. -- 1.11 percent versus 11 1.08. 12 Q. Okay. Let's talk about -- 13 A. So they're basically -- I mean it -- as -- 14 It would, I -- I -- I suggest, be an 15 indication that this is a confounding variable because 16 the odds ratio is bas -- basically eliminated. 17 Q. Have you done a powering analysis of this 18 double-control calculation? 19 A. A power analysis, no. 20 Q. You have no idea whether this is adequately 21 powered. 22 A. Oh, it's -- I -- there's -- 23 There's never been a power analysis of 24 anything related to McGovern. 25 Q. You don't know whether this calculation --</p>

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<p style="text-align: right;">Page 325</p> <p>1 A. I don't -- I mean why are -- 2 What is the issue? The power to do what? I 3 don't know what you're asking. 4 Q. You're analyzing a population of 270 persons 5 and 372 persons, totaling approximately 600 people; 6 correct? 7 A. So what's your -- what's your hypothesis? 8 Q. My question is: If the McGovern study was, 9 in your words, a relatively small population based on 10 the incidence of infection and was therefore 11 unreliable, -- 12 A. Yeah. 13 Q. -- you've cut the population in half. 14 A. Okay. 15 Q. Doubly unreliable. 16 A. Well whether it's double or not, I -- it's 17 not -- it's un -- it's unclear. 18 Q. More unreliable. 19 A. It -- it will be more -- more -- it will 20 have less -- 21 The study would have -- would have even less 22 power, that's true. 23 Q. More unreliable. 24 A. What do you mean by "reliable?" 25 Q. More variance.</p>	<p style="text-align: right;">Page 327</p> <p>1 Q. There would be less variance. 2 A. Oh, if you -- if you -- if you restricted 3 both of those, but I mean that's not your only option. 4 If you restricted it to those groups and had an 5 increased sample size, that would -- that would 6 certainly give you more power. 7 Q. Yeah. It would -- it would be a more 8 accurate representation of whether those two variables 9 were confounders or not; correct? 10 A. If that's what you were interested in. 11 Q. Okay. It would be a more accurate 12 representation as to whether there in fact is an 13 increased odds ratio; correct? 14 A. For -- for -- 15 Q. The use of the device and the outcome of 16 infection. 17 A. The use of the device. It would give a 18 better estimate of that, yes. 19 Q. Okay. The recent Augustine study does that; 20 correct? 21 A. The -- this is the published -- the one that 22 was just published? 23 Q. Yeah. 24 A. Well, I mean the recent study has its own -- 25 has a -- has the potential for bias that is also in</p>
<p style="text-align: right;">Page 326</p> <p>1 A. More variance, yes. 2 Q. If anything, the best way to figure out 3 whether the thromboprophylaxis and the antibiotic 4 confounded the results in a population of patients who 5 were subjected to Bair Hugger warming versus Hot Dog 6 warming would be to look at a larger sample size when 7 both of those variables are controlled; correct? 8 A. Well one would have to look at what the -- 9 What I think is needed is a proper 10 protocol -- 11 Q. Okay. 12 A. -- which would address the issue of power, 13 and you would have to specify what magnitude of effect 14 you wanted -- wanted to detect, -- 15 Q. Okay. 16 A. -- and this, as far as I can tell, was never 17 done by this group. 18 Q. Okay. I'm going to ask the question again 19 because that didn't respond to it. 20 A better analysis than what you have done 21 here with respect to controlling for both var -- 22 variables would be to look at a larger population of 23 patients who received the same thromboprophylaxis and 24 the same antibiotic; correct? 25 A. Well --</p>	<p style="text-align: right;">Page 328</p> <p>1 McGovern. 2 Q. Okay. But my question is different. The 3 recent Augustine article has a larger patient 4 population; -- 5 A. It's a larger patient population. 6 Q. -- correct? 7 A. It is a larger patient population. I think 8 it is, yes. 9 Q. And the article notes that there was no 10 change in the thromboprophylaxis or the antibiotic 11 regimen; correct? 12 MR. GORDON: Object to the form of the 13 question, assumes facts -- mis -- it completely 14 misstates the evidence. 15 A. I -- the -- the -- 16 The paper says very little about -- very -- 17 very little detailed about -- about -- about the 18 population. I think it says that, yes. 19 Q. Okay. So we've established that it's a 20 larger population and that the study does say that 21 there was not a change in the thromboprophylaxis or 22 antibiotic; is that correct? 23 MR. GORDON: Counsel, it doesn't -- it 24 doesn't say that. Let him read it if you're going to, 25 you know, make it up, make up stuff.</p>

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<p style="text-align: right;">Page 329</p> <p>1 THE WITNESS: Where specifically does it say</p> <p>2 that?</p> <p>3 MR. SACCHET: Okay.</p> <p>4 THE WITNESS: Have you got it?</p> <p>5 (Exhibit 28 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. SACCHET:</p> <p>8 Q. Is this a copy of the recent Augustine</p> <p>9 publication in Orthopedic Reviews?</p> <p>10 A. Yes, it is.</p> <p>11 Q. Okay. We can see that on page one there is</p> <p>12 a subject header entitled "Materials and Methods;"</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. In the bottom right-hand corner.</p> <p>16 And it says, "This study is designed to</p> <p>17 investigate periprosthetic joint infection (PJI) rates</p> <p>18 while using FAW (Bair Hugger, 3M, St. Paul, Minnesota,</p> <p>19 USA) compared with air-free CFW (HotDog, Augustine</p> <p>20 Temperature Management, Eden Prairie, USA);" correct?</p> <p>21 A. Yes.</p> <p>22 Q. The next paragraph says, "Each hospital</p> <p>23 report shares a study design similar to the McGovern</p> <p>24 study;" correct?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 331</p> <p>1 Q. Demographics are different than whether</p> <p>2 there were changes to the surgical and antibiotic</p> <p>3 prophylaxis protocols; correct?</p> <p>4 A. They are diff -- they are, but I mean all --</p> <p>5 all I'm -- all I'm indicating is that details --</p> <p>6 Q. Okay.</p> <p>7 A. -- related to what was done in this study</p> <p>8 are pretty skimpy.</p> <p>9 Q. Have you tried to investigate the details</p> <p>10 that you would otherwise like to know?</p> <p>11 A. Oh. I mean you can look at any other paper.</p> <p>12 I mean there's lots of reports on the -- on the -- on</p> <p>13 the characteristics of the patients, what's the age</p> <p>14 distribution of the patients that they're looking</p> <p>15 at, --</p> <p>16 Q. Have you contact --</p> <p>17 A. -- how many males, how many females there</p> <p>18 were, --</p> <p>19 Q. Okay.</p> <p>20 A. -- what is the racial distribution of the --</p> <p>21 Q. Okay.</p> <p>22 A. -- of the -- of the paper. I mean there's</p> <p>23 a -- the --</p> <p>24 The list of things that are not here --</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 330</p> <p>1 Q. "In each study, a baseline PJI rate was</p> <p>2 determined for the FAW control group over a one-year</p> <p>3 period of time. FAW was then discontinued, and the</p> <p>4 hospital switched to air-free CFW warming;" correct?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. The top of the next column says,</p> <p>7 "Only hospitals reporting that no other significant</p> <p>8 changes were made to their surgical and antibiotic</p> <p>9 prophylaxis protocols during the study period</p> <p>10 qualified to be part of this study." Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. It says that there were no changes to</p> <p>13 antibiotic prophylaxis protocols; correct?</p> <p>14 A. That's what it says, yes.</p> <p>15 Q. Do you have any reason to doubt that?</p> <p>16 A. I -- I don't know. I mean that's what --</p> <p>17 that's what it says. I don't -- it -- it --</p> <p>18 I mean we have very little detail here</p> <p>19 about -- about any variables other than the -- other</p> <p>20 than the device that was used --</p> <p>21 Q. Okay. Do you have any --</p> <p>22 A. -- on the patients or --</p> <p>23 I mean there's no table here giving basic</p> <p>24 demographics about the -- about the patient</p> <p>25 population.</p>	<p style="text-align: right;">Page 332</p> <p>1 A. -- is pretty remarkable.</p> <p>2 Q. What is here? There's a statement that says</p> <p>3 "Only hospitals reporting that no other significant</p> <p>4 changes were made to their surgical and antibiotic</p> <p>5 prophylaxis protocols during the study period</p> <p>6 qualified to be part of this study."</p> <p>7 A. Okay.</p> <p>8 Q. Do you have any basis, scientific or</p> <p>9 otherwise, to doubt the veracity of that statement?</p> <p>10 A. No.</p> <p>11 Q. If we look at Table 1, there are three</p> <p>12 centers denominated in the table; correct?</p> <p>13 A. That's correct.</p> <p>14 Q. And the first center has broken down between</p> <p>15 conductive fabric and forced air; correct?</p> <p>16 A. Yes.</p> <p>17 Q. And the odds ratio, based on the increase in</p> <p>18 infection from the use of forced air instead of</p> <p>19 conductive fabric, is 4.59 as reported in this study;</p> <p>20 correct?</p> <p>21 A. That's what they report, yeah.</p> <p>22 Q. Okay. That's the question.</p> <p>23 The second center also evaluates the change</p> <p>24 from conductive fabric to forced air and it finds an</p> <p>25 odds ratio of 11.47 as reported in Table 1; correct?</p>

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<p>1 A. That's what they report.</p> <p>2 Q. Both of those odds ratios are higher than</p> <p>3 what was reported in the McGovern study; correct?</p> <p>4 A. That's true.</p> <p>5 Q. The second odds ratio of 11.47 is almost</p> <p>6 three times the size of what was reported in the</p> <p>7 McGovern study; correct?</p> <p>8 A. That's the -- the --</p> <p>9 You're -- you're referring to just the point</p> <p>10 estimate.</p> <p>11 Q. Just the odds ratio.</p> <p>12 A. Just the point estimate.</p> <p>13 Q. Yeah, that's the question.</p> <p>14 A. It is large. It is large, yes.</p> <p>15 Q. Okay. And the center three, in all</p> <p>16 fairness, reported a 1.33 odds ratio; correct?</p> <p>17 A. That's right.</p> <p>18 Q. The multi-center pooled results based on</p> <p>19 those three institutions totaling a population of over</p> <p>20 2,000 persons --</p> <p>21 Correct?</p> <p>22 A. Yes.</p> <p>23 Q. -- found a collective odds ratio of 4.28;</p> <p>24 correct?</p> <p>25 A. That's right.</p>	<p>1 interval is still 10.</p> <p>2 Q. It's half the size of the confidence</p> <p>3 interval you reported in the Jensen reanalysis;</p> <p>4 correct?</p> <p>5 A. The --</p> <p>6 For that particular association, yes. But</p> <p>7 it's not that different from the confidence interval</p> <p>8 that was reported in McGovern.</p> <p>9 Q. Okay. If we could --</p> <p>10 A. May I --</p> <p>11 There are other aspects of this -- of</p> <p>12 this -- of this --</p> <p>13 Q. I haven't asked about them, so perhaps --</p> <p>14 A. I know you haven't asked about them, but</p> <p>15 you --</p> <p>16 Q. -- perhaps you can explain them when Mr.</p> <p>17 Gordon --</p> <p>18 A. Okay.</p> <p>19 Q. -- asks you some questions.</p> <p>20 With respect to the conclusions that you</p> <p>21 offer in the epi section of your report --</p> <p>22 MR. GORDON: What section?</p> <p>23 Q. -- the epidemiology section of your report</p> <p>24 regarding drawing causal inferences, there is that</p> <p>25 part of your report; right?</p>
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<p>1 Q. That is higher than what's reported in the</p> <p>2 McGovern study; correct?</p> <p>3 A. That point estimate is higher.</p> <p>4 Q. It's doubled in the size of the odds ratio</p> <p>5 of 2.16 that you reported in your study.</p> <p>6 A. It's twice -- twice that, yes.</p> <p>7 Q. It's four times the size of the odds ratio</p> <p>8 that you reported when controlling for both the</p> <p>9 thromboprophylaxis and the antibiotic; correct?</p> <p>10 A. That's correct.</p> <p>11 Q. The population is four times the size.</p> <p>12 A. That's --</p> <p>13 Is it four times?</p> <p>14 Q. Your population was approximately 600</p> <p>15 persons.</p> <p>16 A. Oh, oh, I see that's how you use that.</p> <p>17 Yeah, that's true. Yes.</p> <p>18 Q. Okay. Based on this size of the</p> <p>19 population -- well strike that.</p> <p>20 The p-value for the multi-center pooled</p> <p>21 result is .002; correct?</p> <p>22 A. That's right.</p> <p>23 Q. That is a statistically significant p-value;</p> <p>24 correct?</p> <p>25 A. That is. The -- the -- the confidence</p>	<p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 MR. GORDON: Are you talking about</p> <p>4 "Causation findings," that section?</p> <p>5 THE WITNESS: Yeah, I think that's what he's</p> <p>6 citing.</p> <p>7 MR. SACCHET: Yeah. That was inartful.</p> <p>8 Q. The first factor that you analyzed was the</p> <p>9 temporality --</p> <p>10 A. Yeah.</p> <p>11 Q. -- of -- of this -- of this data.</p> <p>12 You agree that temporality is met with</p> <p>13 respect to the Bair Hugger and the risk of increased</p> <p>14 infection, however; correct?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Okay. You also assume that it's possible</p> <p>17 that temporality may be met with respect to the</p> <p>18 thromboprophylaxis; correct?</p> <p>19 A. Yes.</p> <p>20 Q. We discussed earlier that the McGovern study</p> <p>21 states that the thromboprophylaxis is applied</p> <p>22 postoperatively; correct?</p> <p>23 A. Yes.</p> <p>24 Q. You --</p> <p>25 Do you know the rate in which an infection</p>

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<p>1 forms on a prosthetic upon a bacteria landing on the 2 prosthetic? 3 Let me rephrase. It was not a good 4 question. 5 Do you know how quickly an infection may 6 manifest after a bacteria lands on a prosthetic 7 implant? 8 A. No, I don't. I mean I -- the -- 9 Using the -- this part of the -- the 10 protocol, it is the same for -- for -- for McGovern's 11 study as it was for, you know, the Jensen study, 12 and -- and so they were -- they were using the same 13 method, so whatever the temporality is related to that 14 variable I assume is about the same. 15 Q. So my question, though, is: You don't know 16 whether or not a deep joint infection could occur 17 within an hour of a bacteria landing on the implant. 18 A. Could it have -- I'm not -- 19 I don't know how long it takes. It often -- 20 it -- it may take longer, and may take longer for the 21 diagnosis to come -- come in. 22 Q. It could be shorter than an hour. 23 MR. GORDON: Objection, lack of foundation. 24 A. I don't -- I don't know how long it takes. 25 Q. You don't know.</p>	<p>1 kills whatever happened to be there. 2 Q. You're talking about the thromboprophylaxis, 3 which is a blood thinner; correct? 4 A. Okay. The blood thinner, whatever effect 5 that is having. 6 Q. Yeah. 7 A. I don't know -- 8 Q. You don't know whether there is an effect. 9 A. Don't -- I -- 10 I don't know. There is an association -- 11 Q. Okay. 12 A. -- in -- in this particular study, -- 13 Q. Okay. 14 A. -- so that -- which -- which would suggest 15 if it's not a causal effect, it's at least -- it's -- 16 it's confounded by the same types of factors that 17 could be confounding the association that -- that -- 18 with the device that's being reported by McGovern. 19 Q. But in the event that an infection does in 20 fact occur within hours of a surgery, application of a 21 thromboprophylaxis a day later does not satisfy 22 temporality. 23 MR. GORDON: Objection, lack of foundation, 24 incomplete hypothetical, assumes facts not in 25 evidence.</p>
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<p>1 A. It's not -- it's not reported. I think it's 2 reported how long after the surgery -- 3 Q. Up to 60 days; correct? 4 A. Up to 60 days. But some of that I assume is 5 lab time and all that stuff. 6 Q. Yeah. 7 A. And so who knows? 8 Q. Okay. 9 A. It's not addressing the question that you're 10 asking I don't think. 11 Q. Well -- yeah. So my question really is: To 12 the extent that a deep joint infection may occur 13 within a matter of hours after surgery, temporality is 14 not met in the event that the thromboprophylaxis is 15 applied a day after the surgery. 16 A. If it occurs within hours. Well I mean -- 17 Q. The bacteria causes an infection within a 18 matter of hours -- 19 A. Yeah, but it -- what -- 20 You're not observing it until 60 days later. 21 Q. That's possible. But of course -- 22 A. So if you're observing it at that point -- 23 I mean the infection could have started 24 within hours and then you apply the -- imply 25 the -- apply the -- the anti -- antibiotic and it</p>	<p>1 A. I didn't analyze the temporal -- the -- how 2 long it took for the -- for the -- how -- when -- when 3 the infection -- infection occurred. 4 Q. Uh-huh. 5 A. Those data I don't think were reported on -- 6 on the data that I was looking at. 7 Q. So you don't know whether temporal -- 8 A. So I don't know whether the in -- there was 9 an infection at that point in time. I -- the data -- 10 When I compared the dates of the diagnosis 11 to when the surgery was done, I don't recall there 12 being -- I mean I went over the inci -- incidences, I 13 don't recall instances where they were diagnosed on 14 the same day. 15 Q. Okay. But you're not sure whether 16 temporality is satisfied in all cases with respect to 17 the thromboprophylaxis because you don't know how 18 quickly an infection manifests; is that true? 19 A. I -- I didn't specifically look at that. I 20 suspected that it was, but it -- it -- it -- it -- 21 it -- it's possible that it wasn't. 22 Q. You don't know. 23 A. I -- I don't know. I don't -- I don't know. 24 Q. Okay. 25 A. But there again, I mean the temporality is</p>

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<p style="text-align: right;">Page 341</p> <p>1 important for finding the association for what 2 occurred during the time period that -- that the 3 particular form of prophylaxis was applied, because 4 that could be -- it -- it could be in fact due to 5 something else because of the way this study was done. 6 It was only done by looking at certain dates. So what 7 happened? And of course a lot of things could be 8 happening during these dates, because as -- as the -- 9 this -- this study is related to -- 10 All the changes that were taking place with 11 regard to SSI, which quite possibly were also 12 affecting the -- the -- the deep joint infections, 13 were taking place during this time period, and so 14 that -- it could be something in that that is being 15 indirectly controlled when I'm controlling for the 16 thromboprophylaxis. 17 Q. The bottom line is that there's no doubt 18 temporality is satisfied with respect to the Bair 19 Hugger and incidence of infection; however, there is 20 potential doubt with respect to any of the other 21 factors that you've noted in your report. 22 MR. GORDON: Object to the form of the 23 question, lack of foundation, assumes facts not in 24 evidence. 25 A. There is -- there's the potential --</p>	<p style="text-align: right;">Page 343</p> <p>1 really -- to really be able to -- to -- to nail it 2 down -- 3 Q. Okay. 4 A. -- as to when it is. I -- 5 Q. Thank you. 6 A. I suspect it probably is, but it's unclear. 7 And I think I say -- well it -- it's -- 8 I think it's potentially controlled for, 9 yes. 10 Q. Okay. 11 A. It's not -- 12 Q. It's unclear. 13 A. Yes. 14 Q. The second factor with respect to causal 15 inference is the strength of association; correct? 16 A. Yes. 17 Q. And as to that factor, unlike temporality, 18 it is not a prerequisite to drawing causal inference; 19 correct? 20 A. Well it helps to -- to establish that the 21 association is temp -- is -- is in fact causal because 22 otherwise it could easily be confounded with something 23 else. 24 Q. It helps, but it is not required as it is in 25 temporality; correct?</p>
<p style="text-align: right;">Page 342</p> <p>1 Q. Let me ask the question again. There's no 2 question that temporality is satisfied with respect to 3 the Bair Hugger. You've said as much in your report. 4 A. Yes. 5 Q. There is a question as to whether 6 temporality is satisfied with respect to the 7 thromboprophylaxis and any other of the -- of the 8 measures that were part of the SSI bundle. 9 MR. GORDON: Same objections. 10 Q. You don't know whether temporality is 11 satisfied as to those variables; do you? 12 A. With regard to -- 13 Q. The thromboprophylaxis. Do you know? 14 A. -- thromboprophylaxis -- 15 Q. Do you know? 16 A. I don't know exactly when it -- when it 17 was -- we -- 18 We don't have data on the timing -- 19 Q. Okay. 20 A. -- of it, but -- 21 Q. So you don't know. 22 A. So -- 23 Q. It's really "yes" or "no." 24 A. I -- 25 Well I don't have sufficient detail to</p>	<p style="text-align: right;">Page 344</p> <p>1 A. Well it's one of the factors that's looked 2 for, and in fact one of the factors that was addressed 3 that -- that Samet uses. 4 Q. The question is different and that is: 5 Temporality is a required factor to draw causal 6 inference; correct? 7 A. Yes. 8 Q. The strength of association -- 9 A. Is another factor that -- 10 Q. -- is another factor, but is not a 11 prerequisite for drawing causal inference. 12 A. Okay. 13 Q. Okay. The strength of association goes to 14 the magnitude of causation as opposed to the presence 15 of causation; correct? 16 MR. GORDON: Object to the form of the 17 question. 18 Q. You stated earlier -- 19 A. It's not looking at the mag -- but the -- 20 I don't know what you mean by the magnitude 21 of the causation. 22 Q. The odds -- 23 A. It's either causing or it's not causing. 24 Q. The odds ratio -- 25 A. The association has a magnitude, so I'm not</p>

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<p style="text-align: right;">Page 345</p> <p>1 sure what you're --</p> <p>2 Q. Okay.</p> <p>3 A. -- what you're saying.</p> <p>4 Q. Is the association measured by the odds</p> <p>5 ratio?</p> <p>6 A. The magnitude of association, yes.</p> <p>7 Q. Yes. So with respect to a number such as</p> <p>8 3.8, that signifies the magnitude of the association</p> <p>9 as reported in McGovern.</p> <p>10 A. That -- that -- that is a point estimate of</p> <p>11 magnitude --</p> <p>12 Q. Okay.</p> <p>13 A. -- of association, yes.</p> <p>14 Q. Okay. And that's different than a simple</p> <p>15 determination of causation.</p> <p>16 A. Yes. It's, of course, not just the point</p> <p>17 estimate, --</p> <p>18 Q. Yes.</p> <p>19 A. -- it's the precision of the estimate, so</p> <p>20 you have to take into account the confidence interval</p> <p>21 as well.</p> <p>22 Q. An odds ratio of less than two can show</p> <p>23 causation; correct?</p> <p>24 A. It -- it might, yes.</p> <p>25 Q. Yes.</p>	<p style="text-align: right;">Page 347</p> <p>1 Q. Okay. And as we've established, if an odds</p> <p>2 ratio is above 2.0, that signifies a doubling of the</p> <p>3 risk; correct?</p> <p>4 A. For the point estimate.</p> <p>5 Q. Okay.</p> <p>6 A. That's --</p> <p>7 The precision of that estimate is obviously</p> <p>8 also relevant.</p> <p>9 Q. Yeah. And the Augustine 2007 paper reports</p> <p>10 an odds ratio for the multi-center data above four;</p> <p>11 right? I believe that's what it was.</p> <p>12 A. That's what's reported, yes.</p> <p>13 Q. Okay.</p> <p>14 MR. SACCHET: Can I have a time check, Mr.</p> <p>15 Stirewalt?</p> <p>16 THE VIDEOGRAPHER: Six hours and 20 minutes</p> <p>17 we've been going, forty minutes remaining.</p> <p>18 Q. Are you aware of the difference in the legal</p> <p>19 standard versus scientific standard for drawing causal</p> <p>20 inference?</p> <p>21 MR. GORDON: Objection, object to the form,</p> <p>22 also lack of foundation.</p> <p>23 A. I'm not -- I don't -- not sure what you're</p> <p>24 asking.</p> <p>25 Q. Do you know whether as a matter of law it's</p>
<p style="text-align: right;">Page 346</p> <p>1 And you report that the odds ratio with</p> <p>2 respect to Albrecht 10 using Fisher's exact is 2.76;</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. You also report that the odds ratio when</p> <p>6 applying one additional infection in each arm of the</p> <p>7 study, according to Mr. Reed's testimony, results in</p> <p>8 an odds ratio of 2.89; correct?</p> <p>9 A. I think so.</p> <p>10 Q. Footnote one of your report.</p> <p>11 A. I think that's right. I presume --</p> <p>12 Well 2.886 actually I think it is. Yes.</p> <p>13 Q. That's --</p> <p>14 Oh, my apologies. I said 2.89.</p> <p>15 With respect to when you control for the</p> <p>16 thromboprophylaxis using Albrecht Exhibit 10, the odds</p> <p>17 ratio is 2.16; correct?</p> <p>18 A. Yes, I think it's right.</p> <p>19 Q. You did not report an odds ratio when only</p> <p>20 controlling for the antibiotic; correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Aside from when you controlled both</p> <p>23 variables, all of the odds ratios that we just</p> <p>24 discussed are above 2.0; correct?</p> <p>25 A. All of those, yes.</p>	<p style="text-align: right;">Page 348</p> <p>1 okay to rely on one observational study --</p> <p>2 MR. GORDON: Same --</p> <p>3 Q. -- to prove causation?</p> <p>4 MR. GORDON: Same objection.</p> <p>5 A. I am not a lawyer, I've not studied law, so</p> <p>6 I'm not -- I don't know what the -- what the</p> <p>7 definitions are that are used.</p> <p>8 Q. You didn't opine on that in your report;</p> <p>9 correct?</p> <p>10 A. No. No.</p> <p>11 Q. Okay. With respect to the variable of</p> <p>12 consistency, which is the third factor that both you</p> <p>13 and Dr. Samet considered with respect to causal</p> <p>14 inference, even inconsistent results do not rule out</p> <p>15 causal nexus; correct?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 A. What do you --</p> <p>19 If they're inconsistent, then it -- it's</p> <p>20 going -- going to make it more difficult to determine</p> <p>21 that the association is -- is causal.</p> <p>22 Q. But you can still draw a causal inference</p> <p>23 even with inconsistent results.</p> <p>24 MR. GORDON: Same objection.</p> <p>25 A. It really depends on what -- what you're</p>

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<p style="text-align: right;">Page 349</p> <p>1 looking at. I mean in the abstract I don't -- I have</p> <p>2 a hard time of knowing exactly what you're talking</p> <p>3 about.</p> <p>4 Q. Do you agree with the statement provided in</p> <p>5 The Reference Manual on Epidemiology that inconsistent</p> <p>6 results do not necessarily rule out a causal nexus?</p> <p>7 A. Yes.</p> <p>8 Q. You disagree with that?</p> <p>9 A. No, I would agree with that.</p> <p>10 Q. You agree with that.</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Are you aware of any inconsistent</p> <p>13 results with respect to the Bair Hugger causing deep</p> <p>14 joint infections?</p> <p>15 A. I -- I'm not --</p> <p>16 I don't agree with the idea that it -- it --</p> <p>17 that the causality has been established. If what</p> <p>18 you're asking for is consistency of the</p> <p>19 association, --</p> <p>20 Q. I can rephrase.</p> <p>21 A. -- that -- that's a little different.</p> <p>22 That's -- certainly the --</p> <p>23 I mean basically what we have is the</p> <p>24 Augustine paper and the McGovern paper. Those</p> <p>25 published associations are -- are consistent.</p>	<p style="text-align: right;">Page 351</p> <p>1 amount of particles over the surgical site?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, lack of foundation.</p> <p>4 A. That does not --</p> <p>5 Q. Increase particles over the surgical site.</p> <p>6 A. Well if you're talking about --</p> <p>7 You're reducing it then for particles. I</p> <p>8 mean we -- we've talked about --</p> <p>9 Q. Yeah. I'm just asking just this question.</p> <p>10 A. -- discussed all of that on the record --</p> <p>11 Q. Just this question.</p> <p>12 A. -- and I'm --</p> <p>13 I mean there have been several studies that</p> <p>14 have looked at particle distribution associated with</p> <p>15 the -- with the -- with the use of Bair -- Bair</p> <p>16 Hugger.</p> <p>17 Q. The question is: Are you aware of any</p> <p>18 studies that do not show an increase in particles over</p> <p>19 the surgical site from the Bair Hugger? That's the</p> <p>20 question. "Yes" or "no."</p> <p>21 MR. GORDON: Same objection.</p> <p>22 A. I have not -- haven't really investigated</p> <p>23 that -- that field of how -- of what all the studies</p> <p>24 are --</p> <p>25 Q. On what basis --</p>
<p style="text-align: right;">Page 350</p> <p>1 Q. So there are two studies and they're both</p> <p>2 consistent; correct?</p> <p>3 A. Those two studies agree with each other,</p> <p>4 apparently.</p> <p>5 Q. Are you aware of any other observational</p> <p>6 studies that have been conducted that are inconsistent</p> <p>7 with those two studies?</p> <p>8 A. Those are the only studies that I'm aware of</p> <p>9 that have been -- that -- that have compared Bair</p> <p>10 Hugger and Hot Dog.</p> <p>11 Q. Are you aware of any mechanistic studies</p> <p>12 that have been published that are inconsistent with</p> <p>13 the fact that the Bair Hugger increases the risk of</p> <p>14 deep joint infection?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 A. These are the only two studies that I -- I</p> <p>18 think I said that I know of that have looked at that</p> <p>19 association --</p> <p>20 Q. Okay.</p> <p>21 A. -- between use of the -- of -- the type of</p> <p>22 warming device that was used and risk of infection --</p> <p>23 of deep infection.</p> <p>24 Q. Are you aware of any studies regarding the</p> <p>25 Bair Hugger that show the device does not increase the</p>	<p style="text-align: right;">Page 352</p> <p>1 A. -- that have looked at that.</p> <p>2 Q. On what basis do you conclude, then, that</p> <p>3 there is any consistency, if any, with respect to the</p> <p>4 risk of infection posed by the Bair Hugger?</p> <p>5 MR. GORDON: Object to the form of the</p> <p>6 question.</p> <p>7 A. I -- I mean I think what I was -- what I</p> <p>8 said in my report is that there's --</p> <p>9 Well, at the time this was written --</p> <p>10 Q. One study, yeah.</p> <p>11 A. -- there was one study.</p> <p>12 Q. That no longer applies; correct?</p> <p>13 A. There's -- there's now two.</p> <p>14 Q. And you've just said that those two studies</p> <p>15 are consistent.</p> <p>16 A. Those two studies made the same mistakes and</p> <p>17 they found similar magnitudes of association, so</p> <p>18 that's --</p> <p>19 So now there is a consistency of two.</p> <p>20 Q. Okay. So you're --</p> <p>21 A. Samet was talking about -- was comparing the</p> <p>22 situation of Bair Hugger to cigarettes.</p> <p>23 Q. Could you show me where he does that?</p> <p>24 A. Oh --</p> <p>25 MR. GORDON: Did you mark Samet already?</p>

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<p style="text-align: right;">Page 353</p> <p>1 MR. SACCHET: Yeah, I did. Exhibit 3.</p> <p>2 A. I mean he uses cigarettes -- he -- he talks</p> <p>3 about cigarettes, and that's basically the -- the</p> <p>4 analogy that he is using where he's looking at that</p> <p>5 association.</p> <p>6 Q. Where does he do that?</p> <p>7 A. Okay. Exhibit 3.</p> <p>8 Q. I can speed this up for you, Professor</p> <p>9 Holford, and -- and show you the two places that Dr.</p> <p>10 Samet references tobacco, outside of his history, in</p> <p>11 uncovering the link between tobacco use and cancer, if</p> <p>12 that would be helpful.</p> <p>13 A. Okay.</p> <p>14 Q. On page 10, Dr. Samet says in the second --</p> <p>15 or the first full paragraph, about halfway through,</p> <p>16 "For example, observational designs were used in</p> <p>17 linking cigarette smoking to lung cancer, as some</p> <p>18 people were either current or former smokers and</p> <p>19 others had never smoked. Two basic designs were used;</p> <p>20 the case-control study..." And he goes on to</p> <p>21 explain --</p> <p>22 A. Uh-huh.</p> <p>23 Q. -- those types of studies; correct?</p> <p>24 A. Yes.</p> <p>25 Q. That's one example.</p>	<p style="text-align: right;">Page 355</p> <p>1 those two are --</p> <p>2 He's using tobacco, the experience with</p> <p>3 tobacco in showing the causal association with tobacco</p> <p>4 and -- as I understand it, to try to argue that</p> <p>5 there's a causal association between a warming device</p> <p>6 and the risk of in -- of deep infection.</p> <p>7 Q. So those two sentences in the 17-page report</p> <p>8 in your view show that Dr. Samet is linking tobacco to</p> <p>9 the Bair Hugger.</p> <p>10 A. Well it's not just those --</p> <p>11 MR. GORDON: No, no, no. Take -- take the</p> <p>12 time and go through it page by page and -- and --</p> <p>13 and --</p> <p>14 MR. SACCHET: We don't have time for that.</p> <p>15 MR. GORDON: Well then -- no. Then you're</p> <p>16 not going to just tell him what you've decided are the</p> <p>17 only two sentences and -- and -- and then get him to</p> <p>18 say -- to agree that those are the only two sentences.</p> <p>19 Q. Do you have a recollection to the contrary?</p> <p>20 I've gone through this report and I have made a great</p> <p>21 effort to isolate those two sentences that are the</p> <p>22 only two in my view that exist outside of the</p> <p>23 background section of this report in which Dr. Samet</p> <p>24 describes that he was a senior scientific editor of</p> <p>25 both the 2004 and 2014 report to the Surgeon General</p>
<p style="text-align: right;">Page 354</p> <p>1 A. Yeah.</p> <p>2 Q. The second example is on page 11, in the</p> <p>3 third paragraph, in the last sentence, which says,</p> <p>4 "These arguments are the typical general claims made</p> <p>5 by those seeking alternative explanations for an</p> <p>6 association, and reach back to the strategies employed</p> <p>7 for decades by the tobacco industry," citing Proctor,</p> <p>8 2012 and Samet and Burke, 2001; correct?</p> <p>9 A. Yes.</p> <p>10 Q. Are you aware of any other references to</p> <p>11 tobacco that Dr. Samet makes outside of the first</p> <p>12 three or four pages of the report which describes his</p> <p>13 background?</p> <p>14 A. Well I mean he --</p> <p>15 In this part of his report he is, I think,</p> <p>16 using tobacco as -- I mean it's under the section</p> <p>17 entitled "Evidence Synthesis and Findings on</p> <p>18 Causation."</p> <p>19 Q. Okay.</p> <p>20 A. So this is forming the basis that he's using</p> <p>21 for his justification of causation.</p> <p>22 Q. Where does he link the causation in tobacco</p> <p>23 to causation with the Bair Hugger? Where is that</p> <p>24 express link in this report?</p> <p>25 A. Well no, the point is not that he's -- that</p>	<p style="text-align: right;">Page 356</p> <p>1 regarding the incidence of cancer with respect to</p> <p>2 tobacco use, along with being an associate editor of</p> <p>3 the 1986 report to the Surgeon General. Are you aware</p> <p>4 of any other statement?</p> <p>5 MR. GORDON: Well -- well great, counsel,</p> <p>6 then you have all you need to know about your views.</p> <p>7 MR. SACCHET: Okay.</p> <p>8 MR. GORDON: If you want to know Dr.</p> <p>9 Holford's views, he's not going to rely on your</p> <p>10 representation of your views, he's going to go through</p> <p>11 the document and --</p> <p>12 Q. Sitting here today, do you have any</p> <p>13 recollection of any other statements that Dr. Samet</p> <p>14 has made linking the use of tobacco and the incidence</p> <p>15 of cancer to the use of the Bair Hugger and deep joint</p> <p>16 infection, sitting here right now?</p> <p>17 MR. GORDON: If you want him to answer that</p> <p>18 question, he will go through the report. If you don't</p> <p>19 want --</p> <p>20 MR. SACCHET: You just want me to do that,</p> <p>21 Corey, to use the rest of the time, which I'm not</p> <p>22 going to do.</p> <p>23 MR. GORDON: No. If you don't want a -- if</p> <p>24 you don't want an answer to the question, withdraw it</p> <p>25 and move on.</p>

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<p>1 Q. I'm asking right now: Sitting here today, 2 are you aware of any other statements? 3 MR. GORDON: I'm not going to let him answer 4 that question -- 5 MR. SACCHET: You're going to instruct him 6 not to answer? 7 MR. GORDON: Yeah, I'm going to instruct him 8 not to answer. 9 MR. SACCHET: Okay. Noted for the record. 10 I'll move on. 11 MR. GORDON: If you want him to answer the 12 question, he will go through the report and -- and 13 answer it. 14 Q. Do you agree with Dr. Borak that the 15 particles are relevant to determining the coherency of 16 the scientific evidence to draw a causal inference? 17 MR. GORDON: Object to the form of the 18 question, lack of foundation, mischaracterizes the 19 evidence, assumes facts not in evidence. 20 THE REPORTER: We have 25 minutes left. 21 A. What was the question again? I -- I don't 22 understand -- 23 Q. Do you agree with Dr. Borak that studies 24 involving particles are relevant to the factor of 25 coherency under the Bradford-Hill criteria?</p>	<p>1 A. No. 2 Q. You didn't meet with Dr. Borak on May 19th 3 in Washington, DC? 4 A. I did, but the -- 5 Neither one of us, I think, had written a 6 report to that point. 7 Q. Did you talk about the substance of the 8 report prior to writing the report? 9 A. Of our report? 10 Q. Yeah. 11 A. We didn't discuss our own reports. Our 12 reports are our reports. 13 Q. What did you talk about at the May 19th 14 meeting? 15 A. Generally talked about how -- 16 I mean we're in different fields, -- 17 Q. I understand. 18 A. -- I mean, and so -- 19 Q. Is your field specific to statistics and Dr. 20 Borak's is specific to epidemiology? 21 A. That's more of the division it would be -- 22 it would be, I would say. 23 Q. Was the decision that you would opine on 24 statistics and Dr. Borak would respond on epi? 25 A. Well there is some -- some overlap, but I</p>
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<p>1 MR. GORDON: Same objection. 2 A. I haven't seen the -- the Borak report, as 3 I -- 4 Q. I'm not asking you whether you've seen it, 5 I'm asking whether you agree with Dr. Borak. 6 MR. GORDON: Well you're assuming that 7 you've -- 8 A. Well then how can I -- 9 MR. GORDON: -- accurately characterized 10 what he said. He -- he -- he lacks foundation, 11 counsel, he doesn't know what Dr. Borak said. If you 12 want to ask him if he agrees generally with his -- 13 with whatever statement, you can ask him, but if 14 you're going to pin it on Dr. Borak, he doesn't have a 15 foundation to respond to that because he hasn't read 16 it. 17 Q. Do you disagree with this statement, "The 18 particle count studies might contribute to coherence?" 19 A. I -- I would need to get more of the 20 background of what that statement is -- is -- 21 I mean you're taking one sentence out of -- 22 of a whole report. 23 Q. Did you talk to Borak about your report? 24 A. No. 25 Q. Did you talk to Dr. Borak about his report?</p>	<p>1 mean we were covering different parts of the -- parts 2 of the question, and so he's looking at -- he -- 3 He is considering different issues than what 4 I considered. 5 Q. Well what did you talk about on May 19th? 6 A. Oh. You want me to generate minutes of the 7 meeting? Which I didn't at the -- at the time. 8 We were talking generally about -- about 9 basically how we -- what the issues were that we 10 would -- we would consider in our separate reports. 11 Q. And were there any issues with respect to 12 those views that either one of you were concerned 13 about? 14 MR. GORDON: Object to the form of the 15 question. 16 A. What -- what are you asking? I don't 17 understand the question. 18 Q. Were there any topics of conversation that 19 you were not comfortable with answering without 20 talking to Dr. Borak? 21 A. Not -- not in -- 22 Not that I was looking at in my report, no. 23 Q. Okay. Were there any topics of conversation 24 that questioned whether the Bair Hugger does in fact 25 increase the rate of infection in deep joint</p>

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<p style="text-align: right;">Page 361</p> <p>1 infections?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. What was the question again?</p> <p>5 Q. Was there any conversation as to whether the</p> <p>6 Bair Hugger does in fact increase the rate of deep</p> <p>7 joint infection?</p> <p>8 A. I mean there was general discussion about</p> <p>9 what the -- what the association was and what --</p> <p>10 what -- what the state of the evidence was on -- on</p> <p>11 that association.</p> <p>12 Q. Okay. Is it true that you decided that Dr.</p> <p>13 Borak would be primarily responsible for the causal</p> <p>14 inferences based on epidemiology and you would be</p> <p>15 primarily responsible with respect to the statistical</p> <p>16 application and reanalysis of the McGovern data?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, also lack of foundation.</p> <p>19 A. I'm not sure what you're asking. I --</p> <p>20 Q. Did Dr. Borak ask you to help with drafting</p> <p>21 a report or did 3M ask you?</p> <p>22 A. 3M.</p> <p>23 Q. They approached you independently of Dr.</p> <p>24 Borak?</p> <p>25 A. I think they may have gotten my name from</p>	<p style="text-align: right;">Page 363</p> <p>1 MR. GORDON: Page?</p> <p>2 BY MR. SACCHET:</p> <p>3 Q. If you could please turn to page 22, and</p> <p>4 I'll read the isolated sentence and then we can turn</p> <p>5 back to page 21 and read the preceding sentences.</p> <p>6 A. Page 22?</p> <p>7 Q. Yes.</p> <p>8 A. These are references.</p> <p>9 Q. You might be -- you might be looking at page</p> <p>10 22 of the references as opposed to page 22 of the</p> <p>11 report itself.</p> <p>12 A. Oh, I'm sorry. This is --</p> <p>13 I guess it's actually his CV. Okay. Sorry.</p> <p>14 Q. At the top of page 22 it says, "However, as</p> <p>15 discussed below, the particle count studies might</p> <p>16 contribute to coherence." Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. I'm happy to read the preceding</p> <p>19 sentence if that provides context for you. We can</p> <p>20 look at the subsequent statements if that provides</p> <p>21 context. What would be helpful to you?</p> <p>22 A. "...might contribute to co" --</p> <p>23 "...might contribute to coherence," what</p> <p>24 does he mean by that? I'm not sure --</p> <p>25 Oh.</p>
<p style="text-align: right;">Page 362</p> <p>1 Dr. Borak, but --</p> <p>2 Q. Okay.</p> <p>3 A. -- we did not discuss our reports --</p> <p>4 Q. Okay.</p> <p>5 A. -- together.</p> <p>6 Q. Getting back to the question: Do you have</p> <p>7 any reason to doubt Dr. Borak's statement that</p> <p>8 particles might contribute to the question of</p> <p>9 coherency under the Bradford-Hill criteria?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question, incomplete hypothetical, also lack of</p> <p>12 foundation.</p> <p>13 A. As I say, I haven't read his report, so I</p> <p>14 would have to read his report and study his report to</p> <p>15 know exactly what he's saying. I don't -- I don't</p> <p>16 know --</p> <p>17 You're taking that sentence out of his</p> <p>18 report, and you'll have to give me time to read the</p> <p>19 report and to -- to -- to comment on it.</p> <p>20 Q. Well let's look at the paragraph that he</p> <p>21 discusses because it's three sentences long and I</p> <p>22 don't think --</p> <p>23 It's going to illuminate the issue.</p> <p>24 (Exhibit 29 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 364</p> <p>1 Q. Okay. Well in this section of his report,</p> <p>2 if you turn back a couple pages, on page 20 we see the</p> <p>3 Samet opinion, correct, on the top of the page 20?</p> <p>4 A. Right. Yes.</p> <p>5 Q. And then paragraph 61 says "Strength of</p> <p>6 Association," correct, as the --</p> <p>7 A. Yeah.</p> <p>8 Q. -- subject of that paragraph.</p> <p>9 A. Uh-huh.</p> <p>10 Q. Paragraph 65 has the consistency of the data</p> <p>11 as the topic of that paragraph, and then the</p> <p>12 paragraphs that follow that relate to consistency,</p> <p>13 correct, because paragraph 70 is entitled "Coherence."</p> <p>14 A. Oh, I see. So -- okay. So he's talking</p> <p>15 about consistency. So I wasn't understanding what you</p> <p>16 were saying for that.</p> <p>17 Yeah, it says it "might contribute."</p> <p>18 Q. You disagree with that statement.</p> <p>19 A. It's a pretty vague statement, isn't it? I</p> <p>20 don't know. It might. It might or it might not.</p> <p>21 Q. Okay. Do you disagree with it?</p> <p>22 Might it?</p> <p>23 A. Might it? It might.</p> <p>24 Q. Okay.</p> <p>25 MR. SACCHET: Where are we at?</p>

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<p style="text-align: right;">Page 365</p> <p>1 THE VIDEOGRAPHER: We have 20 -- 21 minutes</p> <p>2 remaining.</p> <p>3 Q. With respect to making causal inferences,</p> <p>4 mechanistic studies may be helpful; correct?</p> <p>5 MR. GORDON: Object to the form of the</p> <p>6 question.</p> <p>7 A. What type of mechanistic studies are you --</p> <p>8 are you indicating?</p> <p>9 Q. So a study or a document that shows the</p> <p>10 biological plausibility or the mechanism of infection</p> <p>11 by which either a drug or a device or --</p> <p>12 A. Okay.</p> <p>13 Q. -- some entity might result in an increased</p> <p>14 outcome at issue.</p> <p>15 A. That can help, yes.</p> <p>16 Q. That can help.</p> <p>17 A. Yes.</p> <p>18 Q. And in the event of two products, for</p> <p>19 example, --</p> <p>20 A. Uh-huh.</p> <p>21 Q. -- would it be helpful if one particular</p> <p>22 product, albeit a different product, had the same</p> <p>23 mechanism of infection as a different product?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>	<p style="text-align: right;">Page 367</p> <p>1 A. Well it -- I mean I think if -- if --</p> <p>2 It depends a lot, I think, on what the --</p> <p>3 what the outcome is on -- on the -- the study that</p> <p>4 you're --</p> <p>5 Q. Same outcome. Let's say --</p> <p>6 A. Infection?</p> <p>7 Q. -- infection and that --</p> <p>8 A. Deep infection?</p> <p>9 Q. -- that's the one you've always been worried</p> <p>10 about.</p> <p>11 A. Okay. So if you're looking at a deep</p> <p>12 infection, if that is the outcome that you're</p> <p>13 measuring with these -- with these two different</p> <p>14 devices, then -- then I think it would be helpful.</p> <p>15 Q. What if it was SSI versus DJI?</p> <p>16 MR. GORDON: Same objection.</p> <p>17 A. It -- there it --</p> <p>18 I mean when you start getting away from it,</p> <p>19 then you really have to get into the details of what</p> <p>20 it is that -- that you're -- what -- what it is you're</p> <p>21 looking at and where the -- where the potential</p> <p>22 differences could be.</p> <p>23 Q. You need to look into those details with</p> <p>24 respect to whether the SSI intervention measures have</p> <p>25 an impact on deep joint infection; correct?</p>
<p style="text-align: right;">Page 366</p> <p>1 A. I guess I would have to know exactly what</p> <p>2 the -- what -- what was -- what -- what you're -- what</p> <p>3 was involved in the two products and which was --</p> <p>4 Q. So in the event that there is one product</p> <p>5 like the Bair Hugger where Dr. Samet opines that one</p> <p>6 of the causal mechanisms is the disruption of airflow</p> <p>7 currents in the operating room that then deposit</p> <p>8 bacteria on the surgical site, if that's the mechanism</p> <p>9 of the Bair Hugger for the sake of an example --</p> <p>10 Do you understand?</p> <p>11 A. Okay.</p> <p>12 Q. -- and if there were another product that</p> <p>13 involved the same mechanism of infection of creating</p> <p>14 currents of air in an operating room that caused</p> <p>15 bacteria to be deposited at the surgical site, those</p> <p>16 are the same mechanisms of infection; correct?</p> <p>17 A. Uh-huh.</p> <p>18 Q. But they're different products, for example.</p> <p>19 A. Okay.</p> <p>20 Q. Because the mechanism is the same, would</p> <p>21 that contribute to coherency of drawing an inference</p> <p>22 about causation?</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question, incomplete hypothetical, assumes facts not</p> <p>25 in evidence, lack of foundation.</p>	<p style="text-align: right;">Page 368</p> <p>1 A. I was not separately studying the -- the SSI</p> <p>2 and -- and DJI, yeah.</p> <p>3 Q. Okay. But with respect to the two devices</p> <p>4 that share the same exact mechanism of infection that</p> <p>5 would both increase the risk of infection, that would</p> <p>6 be helpful in determining whether there was biological</p> <p>7 plausibility or coherency to whether there was an</p> <p>8 increased risk of infection; correct?</p> <p>9 MR. GORDON: Same objection.</p> <p>10 A. It -- it -- it could be.</p> <p>11 Q. Okay.</p> <p>12 A. I don't know.</p> <p>13 Q. Okay.</p> <p>14 A. It depends on the details.</p> <p>15 (Exhibit 30 was marked for</p> <p>16 identification.)</p> <p>17 BY MR. SACCHET:</p> <p>18 Q. This is a document from the CDC; correct,</p> <p>19 Dr. Holford?</p> <p>20 A. It appears to be.</p> <p>21 Q. Are you familiar with HICPAC?</p> <p>22 A. I'm not familiar with it, no.</p> <p>23 Q. Okay. If you could please turn to page 24</p> <p>24 of that document, there is a title that says</p> <p>25 "Nontuberculosis Mycobacterium Infections Associated</p>

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<p style="text-align: right;">Page 369</p> <p>1 With Heater-Cooler Devices." Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And heater-cooler devices are not the</p> <p>4 same as Bair Huggers; correct?</p> <p>5 A. I don't know what devices they're talking</p> <p>6 about.</p> <p>7 Q. Okay. The first sentence of text says, "Dr.</p> <p>8 Perz reviewed points about Nontuberculosis</p> <p>9 Mycobacterium and infections associated with</p> <p>10 heater-cooler devices;" correct?</p> <p>11 A. Yes.</p> <p>12 Q. And this is talking about a device, whether</p> <p>13 or not you know that it's the same as the Bair Hugger</p> <p>14 or not; correct?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question, lack of foundation.</p> <p>17 Q. Does -- does this say that there's a device</p> <p>18 that they're discussing?</p> <p>19 A. There is a device they're discussing.</p> <p>20 Q. Okay.</p> <p>21 A. I don't know --</p> <p>22 I know nothing about it, --</p> <p>23 Q. Yeah.</p> <p>24 A. -- the device.</p> <p>25 Q. I understand that.</p>	<p style="text-align: right;">Page 371</p> <p>1 see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And then on the subsequent page, page</p> <p>4 27, in the last paragraph it says, "The heater-cooler</p> <p>5 unit appears to be harmless from an infection</p> <p>6 perspective, but the water overflow -- overflow bottle</p> <p>7 is likely rarely, if ever, sanitized and is situated</p> <p>8 in front of a fan. Nothing that blows air should be</p> <p>9 in the operating theater, if possible." Do you see</p> <p>10 that?</p> <p>11 A. Yes.</p> <p>12 Q. Do you know why they're concerned about</p> <p>13 things blowing air in the operating room?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question, lack of foundation, it mischaracterizes the</p> <p>16 evidence.</p> <p>17 A. I mean I -- I --</p> <p>18 This is the first I read this, I -- I've</p> <p>19 seen this article. I -- it's -- it's -- it's really</p> <p>20 not my -- my -- not my area.</p> <p>21 Q. You've seen this article?</p> <p>22 A. No, I have not seen it.</p> <p>23 Q. You have not seen it.</p> <p>24 A. That's what I said.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 370</p> <p>1 On page 25 in the second paragraph --</p> <p>2 A. Yeah.</p> <p>3 Q. -- it says, "Two fans are present in the</p> <p>4 heater-cooler."</p> <p>5 A. Uh-huh.</p> <p>6 Q. And it says, "This design is typical for</p> <p>7 this class of device. One fan cools the device's</p> <p>8 internal components, and another, larger fan draws air</p> <p>9 into the machine." Correct?</p> <p>10 A. Yes, that's what it says. Yeah.</p> <p>11 Q. Do you know that the Bair Hugger draws air</p> <p>12 into the machine so it warms patients through the hose</p> <p>13 and into the blanket?</p> <p>14 A. I -- I don't know very much about the de --</p> <p>15 I -- I think that's what it does -- does. I</p> <p>16 don't know a lot of detail about how the -- how the</p> <p>17 Bair Hugger works.</p> <p>18 Q. You don't know a lot of details about how</p> <p>19 the Bair Hugger works?</p> <p>20 A. No.</p> <p>21 Q. Okay. On page 26 there are five bullets</p> <p>22 listed there. Do you see them?</p> <p>23 A. Yes.</p> <p>24 Q. And the third one is, "Direct the exhaust</p> <p>25 from the device away from the sterile field." Do you</p>	<p style="text-align: right;">Page 372</p> <p>1 A. It -- I mean it -- it sort of co --</p> <p>2 coincides with a lot of the concern of what we've been</p> <p>3 talking about today.</p> <p>4 Q. It does; correct?</p> <p>5 A. It's really --</p> <p>6 MR. GORDON: Same objections.</p> <p>7 A. Well I think that was the bas -- basic --</p> <p>8 the -- the purpose of the bubble study and whatnot, is</p> <p>9 to consider --</p> <p>10 Q. Yeah.</p> <p>11 A. -- particles that were distributed in the</p> <p>12 operating room.</p> <p>13 Q. So this is describing a similar concern</p> <p>14 based on the mechanism of infection; correct?</p> <p>15 MR. GORDON: Same objection.</p> <p>16 A. Well it doesn't say why. I mean I -- it</p> <p>17 just --</p> <p>18 Q. One of -- one of the mechanisms is that</p> <p>19 blowing air in the operating room might create</p> <p>20 convection currents that deposit bacteria at the</p> <p>21 surgical site; correct?</p> <p>22 MR. GORDON: Same objections.</p> <p>23 A. I --</p> <p>24 Q. According to Dr. Samet.</p> <p>25 A. Well if it's Dr. Samet, I mean quote Dr.</p>

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<p>1 Samet. It's not --</p> <p>2 That's not my area. I mean we've already</p> <p>3 established what his area is --</p> <p>4 Q. Okay.</p> <p>5 A. -- and this is an area that he feels</p> <p>6 comfortable in and that -- and has -- has -- has done</p> <p>7 work in, and this is not the area --</p> <p>8 Q. You don't feel comfortable in this area.</p> <p>9 A. It's not an area that I -- that I work</p> <p>10 in, --</p> <p>11 Q. Okay.</p> <p>12 A. -- no.</p> <p>13 Q. And so you're unclear about what the</p> <p>14 mechanism of infection that is the issue with respect</p> <p>15 to blowing air in the operating theater; is -- is</p> <p>16 that -- is that your testimony?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question.</p> <p>19 A. It's --</p> <p>20 I mean the authors of this report are</p> <p>21 obviously concerned about blowing -- you know, blowing</p> <p>22 air over water that's -- water that's infected.</p> <p>23 Q. Uh-huh.</p> <p>24 A. I don't know enough about the mechanism of</p> <p>25 the Bair Hugger --</p>	<p>1 con -- conclusions are about -- about causal</p> <p>2 inference.</p> <p>3 Q. Okay.</p> <p>4 A. It was basically the strength --</p> <p>5 Q. Uh-huh.</p> <p>6 A. -- in terms of not only the magnitude of the</p> <p>7 effect, but in terms of the design that was used</p> <p>8 and -- to -- to find those -- those associations and</p> <p>9 whether that is -- the strength of that evidence is --</p> <p>10 was enough to demonstrate a causal -- a causal</p> <p>11 association.</p> <p>12 Q. Do you agree with the statement from The</p> <p>13 Reference Manual on Statistics that "In the end,</p> <p>14 deciding whether associations are causal typically is</p> <p>15 not a matter of statistics alone, but also rests on</p> <p>16 scientific judgment?"</p> <p>17 A. Yes.</p> <p>18 Q. You've only considered the statistical</p> <p>19 aspects; correct?</p> <p>20 A. Well I tried to consider the -- the other</p> <p>21 aspects of -- of the -- of the study as well.</p> <p>22 Q. You said you have no expertise and have not</p> <p>23 delved into the literature as to those additional</p> <p>24 topics; correct?</p> <p>25 A. Of the associated -- of things related</p>
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<p>1 Q. Yeah.</p> <p>2 A. -- to know exactly what is --</p> <p>3 Is there a pool of water in the Bair Hugger</p> <p>4 that it -- that it's blowing air over?</p> <p>5 Q. Okay.</p> <p>6 A. I don't know.</p> <p>7 Q. So you've opined about whether one can draw</p> <p>8 a causal inference as to whether the Bair Hugger</p> <p>9 increases the risk of infection, but you don't</p> <p>10 understand the ways in which the Bair Hugger might in</p> <p>11 fact result in an increase in infection.</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question, misstates his testimony.</p> <p>14 A. I think -- I think that's not -- not an</p> <p>15 accurate description of what -- what I've -- what I've</p> <p>16 been saying. I was looking at the -- the evidence for</p> <p>17 a causal -- a causal association --</p> <p>18 Q. Uh-huh.</p> <p>19 A. -- and does -- that has in -- that has</p> <p>20 basically involved looking at what the -- the design</p> <p>21 and the estimates of effect that were known to me</p> <p>22 at the -- at the time that I did that -- did that</p> <p>23 analysis.</p> <p>24 Q. And that's it.</p> <p>25 A. And that's basically what I was drawing my</p>	<p>1 specifically to these devices. I was primarily</p> <p>2 concentrating on the studies that had been done on the</p> <p>3 epidemiology.</p> <p>4 Q. And those studies are the McGovern study and</p> <p>5 the Augustine study, which are the only two</p> <p>6 epidemiologic studies on the risk of infection from</p> <p>7 the Bair Hugger to deep joint infection; correct?</p> <p>8 A. For the Bair -- for the Bair Hugger effect,</p> <p>9 the Bair Hugger/Hot Dog comparison, those were the --</p> <p>10 basically the studies that I was comparing.</p> <p>11 MR. SACCHET: Okay. We're going to look at</p> <p>12 one more document. Maybe two, but --</p> <p>13 (Exhibit 31 was marked for</p> <p>14 identification.)</p> <p>15 BY MR. SACCHET:</p> <p>16 Q. This is another document from the CDC;</p> <p>17 correct?</p> <p>18 MR. GORDON: Objection, lack of foundation.</p> <p>19 THE REPORTER: We have eight minutes left.</p> <p>20 Q. Does the title page of this document,</p> <p>21 professor, show the CDC's logo on it?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And if you could please turn to page</p> <p>24 12 of the document, it states "FDA Device Updates:</p> <p>25 Flexible Endoscopes and Heater Coolers;" correct?</p>

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<p>1 A. Yes.</p> <p>2 Q. Okay. If you could turn to page 15 of the</p> <p>3 document, there are a number of bullet points;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And the fourth one down says, "The</p> <p>7 orientation of the vent(s) on the devices may or may</p> <p>8 not direct the fan exhaust toward the patient or the</p> <p>9 sterile field. The exhaust from cooling fans may also</p> <p>10 play a role in the airflow within the OR, possibly</p> <p>11 facilitating movement of the aerosolized NTM into the</p> <p>12 sterile field." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Is that the same mechanism of infection that</p> <p>15 Dr. Samet described in his report?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, lack of foundation, assumes facts not</p> <p>18 evidence, mischaracterizes the testimony.</p> <p>19 A. I -- I don't recall the detail of how --</p> <p>20 what Dr. Samet's description was on -- on -- on the --</p> <p>21 on the -- on devices used.</p> <p>22 Q. One of the issues in this litigation that</p> <p>23 was discussed in the McGovern study, which you are</p> <p>24 aware of, is that the Bair Hugger might generate</p> <p>25 convection currents that results in increased</p>	<p>1 MR. GORDON: Okay.</p> <p>2 MR. SACCHET: Yes.</p> <p>3 Q. That's correct.</p> <p>4 A. Okay.</p> <p>5 Q. And this bullet, which is from the CDC that</p> <p>6 we established, says that "The exhaust from cooling</p> <p>7 fans may also play a role in the airflow within the</p> <p>8 OR, possibly facilitating the movement of the</p> <p>9 aerosolized NTM into the sterile field," correct?</p> <p>10 A. It possibly is.</p> <p>11 MR. GORDON: Objection, asked and answered.</p> <p>12 Q. Possibly?</p> <p>13 MR. GORDON: You read it right.</p> <p>14 A. Yes.</p> <p>15 Q. Okay.</p> <p>16 MR. GORDON: Are you asking him if he -- if</p> <p>17 he has any basis for --</p> <p>18 MR. SACCHET: No, I'm not, Corey.</p> <p>19 MR. GORDON: -- saying anything --</p> <p>20 commenting on that?</p> <p>21 MR. SACCHET: Please don't use the rest of</p> <p>22 my time. I'm not going to engage --</p> <p>23 MR. GORDON: Well I want -- I want to get an</p> <p>24 objection. I thought you were just, once again,</p> <p>25 reading the same sentence. If you're asking him to</p>
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<p>1 particles over the surgical site; correct?</p> <p>2 A. Yes. Yes.</p> <p>3 Q. This bullet says that "The exhaust from</p> <p>4 cooling fans may also play a role in the airflow</p> <p>5 within the OR, possibly facilitating movement of the</p> <p>6 aerosolized NTM into the sterile field." Do you see</p> <p>7 that?</p> <p>8 MR. GORDON: Objection, asked and answered.</p> <p>9 Q. You've seen it.</p> <p>10 Does that describe a similar mechanism of</p> <p>11 moving particles or bacteria to the sterile field?</p> <p>12 MR. GORDON: Well wait, wait, wait. You</p> <p>13 started out with talking about convection currents,</p> <p>14 now you're changing gears. What -- what are you</p> <p>15 asking him?</p> <p>16 Q. I'm asking: One of the mechanisms of</p> <p>17 infection described in the McGovern study is the</p> <p>18 movement of particles from air currents generated by</p> <p>19 the Bair Hugger; correct?</p> <p>20 MR. GORDON: Well before you said convection</p> <p>21 currents, not --</p> <p>22 MR. SACCHET: Okay.</p> <p>23 MR. GORDON: You say you're changing that</p> <p>24 now?</p> <p>25 MR. SACCHET: I am.</p>	<p>1 comment on it, I object on the grounds of lack of</p> <p>2 foundation.</p> <p>3 Q. Does this describe a similar mechanism of</p> <p>4 infection as noted by McGovern et al in the study that</p> <p>5 you have reviewed?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question, also lack of foundation, also</p> <p>8 mischaracterizes the evidence.</p> <p>9 A. I'm not sure it --</p> <p>10 It's un -- it's unclear. I mean just that</p> <p>11 sentence, I can't figure out -- I -- I -- I'm not --</p> <p>12 unclear as to whether -- how this relates to what</p> <p>13 McGovern is saying.</p> <p>14 Q. Did you try to shore up your</p> <p>15 misunderstanding or questions about that statement?</p> <p>16 A. Well I mean you just -- you just showed me</p> <p>17 this, --</p> <p>18 Q. Okay. So you -- you didn't investigate --</p> <p>19 A. -- so how could I --</p> <p>20 Q. You didn't investigate this.</p> <p>21 A. Not when --</p> <p>22 No. I mean you asked me this question</p> <p>23 about --</p> <p>24 Q. You didn't know about it.</p> <p>25 A. -- a minute before. I didn't know about</p>

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<p style="text-align: right;">Page 381</p> <p>1 this report, no.</p> <p>2 MR. SACCHET: Okay. I'm going to show you</p> <p>3 one other document.</p> <p>4 (Exhibit 32 was marked for</p> <p>5 identification.)</p> <p>6 BY MR. SACCHET:</p> <p>7 Q. This is a document bearing the Bates number</p> <p>8 3MBH0001 -- 1336; correct?</p> <p>9 A. Yes.</p> <p>10 Q. Have you seen it before?</p> <p>11 A. No.</p> <p>12 Q. The top line says "CONFIDENTIAL - NOT FOR</p> <p>13 EXTERNAL DISTRIBUTION;" correct?</p> <p>14 A. Yes.</p> <p>15 Q. And then the bolded typeface says "Arizant</p> <p>16 forced-air warming and SSI prevention: Talking points</p> <p>17 for sales;" correct?</p> <p>18 A. Yes.</p> <p>19 Q. And it says "Our position." The first line</p> <p>20 is, "There is no evidence that forced-air warming</p> <p>21 (FAW) increases risk of surgical site infections</p> <p>22 (SSIs).";" correct?</p> <p>23 A. That's what it says.</p> <p>24 Q. And there's a comment right next to it;</p> <p>25 correct?</p>	<p style="text-align: right;">Page 383</p> <p>1 right-hand corner, as part of your review?</p> <p>2 A. Any documents that had --</p> <p>3 Q. That had a Bates number bearing the prefix</p> <p>4 3MBH.</p> <p>5 A. I don't recall. I -- al -- although I don't</p> <p>6 know --</p> <p>7 I didn't look carefully at that Bates number</p> <p>8 on all of the documents. I don't recall that.</p> <p>9 Q. Were any internal 3M documents provided to</p> <p>10 you as part of your review of the evidence in this</p> <p>11 case?</p> <p>12 A. No.</p> <p>13 Q. Did you meet with any people from 3M with</p> <p>14 respect to preparing your report?</p> <p>15 A. No, I did not.</p> <p>16 MR. SACCHET: Okay. I will reserve the rest</p> <p>17 of my time.</p> <p>18 THE REPORTER: Off the record, please.</p> <p>19 (Discussion off the record.)</p> <p>20 MR. GORDON: We'll read -- we'll read and</p> <p>21 sign.</p> <p>22 MR. SACCHET: I'd like to make one note.</p> <p>23 THE REPORTER: Let's go back on the record.</p> <p>24 MR. SACCHET: To the extent that Dr. Holford</p> <p>25 has noted in his report that he reviewed documents</p>
<p style="text-align: right;">Page 382</p> <p>1 A. Yes.</p> <p>2 Q. And it says, "Actually, there is evidence</p> <p>3 that FAW use increases risk." Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Do you know who wrote that statement?</p> <p>6 A. No, I don't.</p> <p>7 Q. Do you know whether that statement was</p> <p>8 written by a 3M employee?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question, lack of foundation.</p> <p>11 A. I've never seen this document before, so I</p> <p>12 have no idea.</p> <p>13 Q. Are you surprised that this statement was</p> <p>14 made in a document that's confidential regarding</p> <p>15 Arizant talking points on SSI prevention?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, lack of foundation, misstates --</p> <p>18 mischaracterizes the evidence.</p> <p>19 A. I don't --</p> <p>20 I mean I know basically nothing about this</p> <p>21 document.</p> <p>22 Q. You've never seen it before.</p> <p>23 A. I've never seen it before.</p> <p>24 Q. Okay. Did you look at any documents that</p> <p>25 had a 3M Bates number on it, like this in the bottom</p>	<p style="text-align: right;">Page 384</p> <p>1 provided by 3M with respect to the use of the Bair</p> <p>2 Hugger at particular hospitals in the NHS and that</p> <p>3 those documents were not cited in his report, I'm</p> <p>4 leaving the deposition open.</p> <p>5 THE REPORTER: Off the record, please.</p> <p>6 (Deposition concluded.)</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p style="text-align: right;">Page 385</p> <p>1 CERTIFICATE</p> <p>2 I, Richard G. Stirewalt, hereby certify that</p> <p>3 I am qualified as a verbatim shorthand reporter, that</p> <p>4 I took in stenographic shorthand the deposition of</p> <p>5 THEODORE R. HOLFORD at the time and place aforesaid,</p> <p>6 and that the foregoing transcript is a true and</p> <p>7 correct, full and complete transcription of said</p> <p>8 shorthand notes, to the best of my ability.</p> <p>9 Dated at Deerwood, Minnesota, this 23rd day</p> <p>10 of July, 2017.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17 RICHARD G. STIREWALT</p> <p>18 Registered Professional Reporter</p> <p>19 Notary Public</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	
<p style="text-align: right;">Page 386</p> <p>1 CERTIFICATE</p> <p>2 I, THEODORE R. HOLFORD, hereby certify that</p> <p>3 I have carefully read the foregoing transcript, and</p> <p>4 that the same is a true and complete, full and correct</p> <p>5 transcription of my deposition, except:</p> <p>6 PAGE/LINE CHANGE REASON</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17 THEODORE R. HOLFORD</p> <p>18 Deponent</p> <p>19</p> <p>20 Signed and sworn to before me this ____ day of</p> <p>21 August, 2017.</p> <p>22</p> <p>23 _____</p> <p>24 Notary Public</p> <p>25</p>	

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